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Research on Illegal Prescription Drug Market Interventions

Final

April 1, 2015

Prepared for: Office of National Drug Control Policy (ONDCP)

Prepared by: Abt Associates 4550 Montgomery Avenue Suite 800 North Bethesda, MD 20814

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Introduction

This study was requested by the National Institute of Justice (NIJ) and funded in partnership with the Office of National Drug Control Policy (ONDCP) through the FY2014 Performance Management Process (PMP) Audit Service Contract for the ONDCP High Intensity Drug Trafficking Area (HIDTA) Program.

NIJ initiated the research to collect information on policies, practices, and resources available to the HIDTA program and partnering law enforcement agencies for major crime deterrence, prosecution, and other interventions specific to illegal prescription drug markets. One goal of the HIDTA program is to coordinate intelligence and information sharing and enforcement efforts across federal, state, local, and tribal law enforcement agencies involved in the investigation and prosecution of drug trafficking organizations operating within the HIDTA region, making the HIDTA program a valuable resource for collecting information on drug market interventions.

Since 2008, through the Audit Service Contract, Abt Associates has worked with HIDTA programs across the country to collect information on performance measurement related to training, intelligence and information sharing, and enforcement activity. For this study, the plan was to expand the audit activities to collect information specific to strategies implemented by selected HIDTAs to disrupt the regional illegal prescription drug market through partnerships with the public health or medical communities, training, and the investigation and prosecution of drug trafficking organizations involved in trafficking illegal prescription drugs.

NIJ identified the following three HIDTA regions for this study: the Northwest HIDTA region, which includes multiple counties in the state of Washington; the New Mexico HIDTA region, which includes multiple counties in the state of New Mexico, and the New England HIDTA region, which includes counties in the states of Massachusetts, Connecticut, Rhode Island, New Hampshire, Vermont, and Maine.

The original research goals included identifying interventions applied by the HIDTA to address the regional illegal prescription drug market. We found, however, that we were not able to have conversations with federal law enforcement officials leading major investigations of drug trafficking organizations due to the public nature of this report. Therefore, discussion of law enforcement investigation activity is limited to information from representatives from task forces led by state or local law enforcement agencies, which limited the scope of the investigations that could be discussed.

This report begins by providing background on the illegal prescription drug threat in the United States and the multiple strategies used to divert prescription drugs, and then reviews the range of responses supported by ONDCP, through the HIDTA program, and by state agencies through Prescription Drug Monitoring Programs (PDMPs). The study draws on a variety of sources that include scientific and professional literature, published materials from Federal, state, and local programs, internet searches related to enforcement, education, and prevention, as well as discussions with law enforcement and administrators from state PDMPs. This is a report of our findings.

Illegal Prescription Drug Threat

Over the last two decades, the abuse of controlled prescription drugs (CPDs) has become an increasingly critical public health problem in the U.S.¹ During the 1970s and 1980s, the numbers of persons using CPDs for non-medical purposes (not prescribed or not as prescribed) remained relatively stable, but began to rise in the 1990s, most dramatically for opioid pain relievers and sedatives. By 2010, an estimated 20% of the US population aged 12 and older (52M persons) admitted to non-medical use of CPDs at some point in their lives, and 6% within the past year.² Admission rates for treatment for opiates other than heroin increased by over 300% between 1996 and 2006 and the number of visits to the emergency department for the misuse or abuse of pharmaceuticals increased by over 100% between 2004 and 2011.^{3,4}

Numbers of drug overdose deaths increased almost 300% between 1995 and 2012 and now exceed traffic accidents as the leading cause of death in the United States.⁵ Thirty-nine percent of those deaths in 2012 involved opioid analgesics.⁶ Since 2001, deaths from prescription opioids have been twice as frequent as deaths from heroin and cocaine overdoses combined.⁷ These trends paralleled the rapid growth in physicians' prescribing federally scheduled CPDs. Between 1997 and 2006, the volume of oxycodone dispensed by retail pharmacies increased 678%, hydrocodone (e.g., Vicodin) by 225%, and amphetamines

² Substance Abuse and Mental Health Services Administration. (2011). Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings. (NSDUH Series H-41, HHS Publication No. (SMA) 11-4658. Rockville, MD.

³ Substance Abuse and Mental Health Services Administration. (2008). Office of Applied Studies. Treatment Episode Data Set (TEDS): 1996-2006. National Admissions to Substance Abuse Treatment Services, DASIS Series: S-43, DHHS Publication No. (SMA) 08-4347, Rockville, MD.

- ⁴ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (2012) The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Rockville, MD.
- ⁵ Fingerhut, L.A, & Cox C.S. (1988). Poisoning Mortality 1985-1995. *Public Health Rep.* May-Jun 1998;113(3):218-233; Warner, M., Hedegaard, H., & Chen, L. (2014). Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012. Hyattsville, MD: *National Center for Health Statistics*.
- ⁶ Warner, M., Hedegaard, H., & Chen, L. (2014). Trends in Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012. Hyattsville, MD: *National Center for Health Statistics*.
- ⁷ Warner, M., Chen L., & Makuc, D.M. (2009). Increase in fatal poisonings involving opioid analgesics in the United States, 1999-2006. *National Center for Health Statistics Data Brief.* Sep 2009(22):1-8.

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¹ Paulozzi, L. J., Budnitz, D. S., & Xi, Y. (2006). Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiology and Drug Safety*, *15*(9), 618-627; Hall, A. J., Logan, J. E., Toblin, R. L., Kaplan, J. A., Kraner, J. C., Bixler, D., Paulozzi, L. J. (2008). Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA*, *300*(22), 2613-2620; Paulozzi L.J., Jones C.M., Mack K.A., & RA, R. (2011). Vital signs: overdoses of prescription opioid pain relievers---United States, 1999--2008. *Morbidity and Mortality Weekly Report*, *60*(43), 1487; Paulozzi, L. J., Weisler, R. H., & Patkar, A. A. (2011). A national epidemic of unintentional prescription opioid overdose deaths: how physicians can help control it. *Journal of Clinical Psychiatry*, *72*(5), 589-592.

by 150%.⁸ The trends in opioid prescribing resulted from several developments: the introduction to the market of powerful higher dose synthetic opioids in the 1990s, physicians' growing willingness to use opioids for chronic long-term pain and not just for cancer or end-of-life care, more flexible pain management guidelines by medical societies, and aggressive marketing by pharmaceutical manufacturers. For example, OxyContin, an extended release form of oxycodone erroneously promoted as "abuse-resistant," was introduced to the market in 1996 and, within four years, annual sales went to \$48M to \$1.1B.⁹ In a recent study, Abt Associates estimated that by 2008, physicians were prescribing opioids at an average of over 400 mg of morphine equivalent units per U.S. resident. Regional variation in prescribing abounds however, with per capita rates five times higher in some states than in states with the lowest rates, indicative of widespread inconsistencies in prescribing practices.¹⁰

What are Controlled Prescription Drugs?

Federal laws related to controlled substances were consolidated with passage of the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The objective of this law was "to prevent diversion of controlled substances while assuring an adequate supply for legitimate medical, research, and industrial needs."¹¹ With its passage, Congress created a closed system that allowed federal authorities to monitor manufacture, distribution, and dispensing of controlled substances. Moreover, the law specified that all handlers (e.g., manufacturers, physicians, pharmacists) of controlled substances must be registered with the Drug Enforcement Administration (DEA), must maintain complete and accurate inventories and records, and must provide security for storing controlled substances. Criminal penalties were established for sanctioning unlawful activities. The CSA also authorized the Attorney General to set up annual production quotas for certain controlled drugs. The quotas are set annually by the DEA, and must allow for sufficient quantities to meet legitimate medical and scientific needs in the United States.

⁸ Drug Enforcement Administration. Automation of Reports and Consolidated Orders System (ARCOS), Retail Drug Summary, reports for 1997 and 2006. <u>http://www.deadiversion.usdoj.gov/arcos.</u> Retrieved December 2011.

⁹ Van Zee, A. (2009). The promotion and marketing of oxycontin: commercial triumph, public health tragedy. *American Journal of Public Health*, *99*(2), 221-227.

¹⁰ McDonald, D.C., Carlson, K., & Izrael, D. (2012). Geographic variation in opioid prescribing in the U.S. *Journal of Pain*. Oct 2012;13(10):988-996.

¹¹ Government Accountability Office. (1975). Improvements Needed In Regulating and Monitoring the Manufacture and Distribution of Licit Narcotics (Washington, D.C., GGD-75-102, August 28, 1975). See "Controlled Substances Act," Drug Enforcement Administration, Available at http://www.deadiversion.usdoj.gov/21cfr/21usc/.

The CSA established the five-tiered schedule of controlled substances that is now in effect. Drugs are assigned to one of these categories based upon its medicinal value, harmfulness, and potential for abuse or addiction.¹²

• Schedule I drugs are those that are considered the least safe, have no legitimate medical use in the United States, and have a high potential for abuse. Examples of Schedule I drugs include heroin, marijuana, and LSD.

All other scheduled drugs have legitimate medical use, but differ according to their safety and risks.

- Schedule II drugs have legitimate medical uses but pose serious risks. Abuse of Schedule II drugs may lead to severe psychological or physical dependence. Examples include narcotic analgesics such as, morphine, oxycodone (OxyContin); amphetamines such as, dextroamphetamine (Dexedrine); methylphenidate (Ritalin) and cocaine (for topical anesthesia).
- Schedule III drugs have a potential for abuse, but less than Schedule II drugs. Abuse of Schedule III drugs may lead to moderate or low physical dependence or high psychological dependence. Examples include narcotic analgesics such as, hydrocodone with acetaminophen (Vicodin) and barbiturates such as secobarbital (Seconal).
- Schedule IV drugs have a still lower potential for abuse, although misuse of these drugs may lead to limited physical dependence or psychological dependence. Examples include benzodiazepine such as, diazepam (Valium), lorazepam (Ativan); some barbiturates, such as phenobarbital; and narcotic analgesics such as, propoxyphene (Darvon).
- Schedule V drugs are the least dangerous of all controlled substances, and include codeine preparations, dihydrocodeine preparations, among others.

Drugs not specifically assigned to schedules are considered "unscheduled," and are not considered controlled substances. For all the drugs on the controlled substances schedule, a number of requirements are imposed upon prescribers and pharmacists. Under the CSA, it is unlawful for a practitioner to prescribe or dispense a controlled substance except in the course of medical treatment. Physicians are required by law to have a license that permits them to prescribe controlled substances. Licensing of physicians for the prescribing of controlled substances is done by the DEA, in which physicians are issued a DEA number, which must be recorded on a controlled substance prescription. Similarly, pharmacies are required to obtain a controlled substance license (renewed annually) that allows them to dispense controlled substances. Unlike physicians, pharmacists are not required to obtain separate licenses for themselves.

¹² More specifically, the law directs assignment of drugs to specific schedules according to the following factors: its actual or relative potential for abuse; scientific evidence of its pharmacological effect, if known; the state of current scientific knowledge regarding the drug or other substance; its history and current pattern of abuse; the scope, duration, and significance of abuse; what, if any, risk it poses to the public health; its psychic or physiological dependence liability; and whether the substance is an immediate precursor of a substance already controlled. "Controlled Substances Act," 21 USC Section 811, subsection c.

What is Diversion?

Whereas illicit drugs are manufactured illegally, prescription drugs are produced legally by licensed manufacturers, but can be subsequently diverted into what is estimated to be a multi-billion dollar black market.¹³ The market for CPDs that are used non-medically is supplied by a number of different diversion channels.

Unscrupulous Physicians and Pharmacists

Physicians may provide prescriptions knowingly to individuals who have no legitimate medical need or prescribe them based on inadequate evaluations of patients' needs and fail to provide adequate monitoring. These can include both individual doctors and pain clinics. In order to prevent this, several states have passed laws requiring a physical examination or an evaluation of patient history by a physician prior to prescribing controlled substances.¹⁴ Additionally, some states have also passed a number of laws

related to the oversight, ownership, and operation of pain clinics, requiring, for example, that the clinic is owned by a physician certified in pain management.¹⁵ Furthermore, pharmacists may also verify false prescriptions or sell drugs to patients without prescriptions and cover their tracks by falsifying records or making no record of the transaction.¹⁶

Doctor Shopping

Individuals seeking to obtain prescription drugs for illegitimate purposes can do so by covertly presenting themselves to numerous physicians, thereby obtaining multiple seemingly legitimate prescriptions. While almost all states have laws related to obtaining prescriptions through fraud or misrepresentation, a number of states have passed laws that specifically refer to concealment when seeking a prescription from another doctor. ¹⁷ Without an avenue to share information among doctors and pharmacists, doctor shopping is difficult to Notably, the state of Washington recently passed House Bill 2876, which is considered one of the strictest prescription-related laws in the country. This bill imposes dose limits on individuals who are prescribed painkillers for non-cancer related conditions. It also requires reevaluation of patients who request increasing doses of painkillers, and continuing education for prescribers on the dangers of prescription drug diversion. The bill has also placed additional criteria on who can be considered a pain specialist. The intent of this bill is to disrupt the growing amount of prescribed opiates in the state of Washington (Washington State Department of Health, n.d.).

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¹³ Government Accountability Office. (2002). Prescription Drugs – State Monitoring Programs Provide Useful Tool to Reduce Diversion. Washington, D.C.: Report to the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, GAO-02-634, May 2002.

¹⁴ See the Center for Disease Control and Prevention's compendium of state prescription drug laws related to physical exams available at <u>http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/exam.html</u>. Retrieved February 3, 2015.

¹⁵ See the Center for Disease Control and Prevention's compendium of state prescription drug laws related to pain clinics <u>http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/pain_clinic.html.</u> Retrieved February 3, 2015.

¹⁶ Rigg, K.K., Kurtz, & Surratt, H.L. (2012). Patterns of prescription medication diversion among drug dealers. *Drugs: Education, Prevention, and Policy*. April 2012; 9(2): 145-155.

¹⁷ See the Center for Disease Control and Prevention's compendium of state prescription drug laws related to doctor shopping <u>http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/dr_shopping.html.</u> Retrieved February 3, 2015.

detect. Pharmacists' records are generally restricted to outlets owned by the same firm, and pharmacies do not share these records with one another. Privately or individually owned pharmacies are also not included in any of the larger networks. Information about drugs purchased at other pharmacies is available to pharmacists only if the reimbursement is requested from governments or commercial insurers (because prior approval by these third parties is required for reimbursement). By not requesting reimbursement or paying cash, individuals can avoid alerting third party payers. To address this weakness, almost every state in the country has implemented or is the process of implementing a Prescription Drug Monitoring Program (PDMP) to allow the sharing of information across doctors and pharmacies.¹⁸

Sharing or Selling Pills Obtained Legitimately

Patients who have valid prescriptions may share their pills with individuals with no medical need for the medication. The most recent National Survey on Drug Use and Health (NSDUH) reported that more than half of persons 12 and older who reported obtaining painkillers did so from a friend or relative for free.¹⁹ Others may sell some of their legitimately obtained pills to others, including providing pills to street level dealers who may be selling other illegal drugs. This may occur when there are unused or unwanted medication remaining from a legitimate prescription.²⁰

Prescription Forgery

There are a variety of ways in which individuals can use forged prescriptions to obtain drugs, including stealing prescription pads from physicians; creating counterfeit prescription forms or making copies of real forms; altering legitimate prescriptions; pretending to be prescribing physicians and submitting orders by telephone; among other methods. To reduce prescription forgery and theft of blank prescription forms, states have adopted a variety of different strategies, including issuing serialized prescription forms and issuing tamper-resistant forms.²¹ States have also passed laws requiring patient identification when filling a prescription as a means to reduce fraud.²²

¹⁸ See the National Alliance for Model State Drug Law's status of State Prescription Drug Monitoring Programs (PDMPs) <u>http://www.namsdl.org/library/57F45761-F05E-9DFD-025D8B9326350C27/.</u> Retrieved January 23, 2015.

¹⁹ Substance Abuse and Mental Health Services Administration. (2014). Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD.

 ²⁰ Rigg, K.K., Kurtz, & Surratt, H.L. (2012). Patterns of prescription medication diversion among drug dealers. *Drugs: Education, Prevention, and Policy*. April 2012; 9(2): 145-155: Inciardi, J.A., Surratt, H.L., Kurtz, S. P., & Cicero, T. J. (2007). Mechanisms of prescription drug diversion among drug-involved club- and street-based populations. *Pain Medicine*; 8(2): 171-183.

²¹ See the Center for Disease Control and Prevention's compendium of state prescription drug laws related to tamper-resistant forms <u>http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/forms.html</u>. Retrieved February 3, 2015

²² See the Center for Disease Control and Prevention's compendium of state prescription drug laws related to patient identification http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/id_req.html. Retrieved February 3, 2015.

Thefts and Robberies

Prescription drugs are also obtained by theft from or in transit between manufacturers, distributors, and dispensers, as well as from personal medicine cabinets. Thefts from manufacturers and distributors may be committed by employees or by others with access. Studies conducted by the Government Accountability Office (GAO) during the 1970s reported that the DEA indicated that most theft and pilferage occurred at the retail pharmacy level.²³ Similar conclusions were reached in later GAO studies of Medicaid prescription drug diversion.²⁴ The DEA has published information regarding the extent of diversion of some specific narcotic pain relievers by various forms of theft and robbery from pharmacies, distributors, treatment programs or any other business where controlled substances are stored. During 2003, for example, 205,000 dosage units of OxyContin were reported stolen or lost. Night break-ins accounted for 44% of the total, armed robberies 30 percent, employee pilferage 17%, customer theft 2%, and 8% were lost or stolen in transit.²⁵

Smuggling

Some diversion of prescription drugs into the domestic black market comes by way of smuggling from other countries. Mexico is one neighboring source country with weak controls over pharmaceutical drugs and easy access to the U.S. market via smuggling. Over 95% of opiates in the United States, including heroin, are thought to be smuggled through Mexico, mostly originating in Columbia or Mexico.²⁶ Recently, Mexico has adopted many of the same prescription standards as the United States, but some drugs that require prescriptions in the United States continue to be purchased illegally over the counter in Mexican pharmacies, and then smuggled over the border.²⁷ In December 2001, almost a million dosage units of OxyContin that were believed to be destined for the U.S. were stolen from a pharmaceutical

²⁵ Drug Enforcement Administration, Diversion Control Program. OxyContin® Theft & Loss Incidents January 2000 through June 2003. Available at www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxylosses_oct2003_1.pdf. Retrieved December 2004.

²³ Government Accountability Office. (1972) Efforts to Prevent Dangerous Drugs From Illicitly Reaching the Public. Washington, D.C., Report to Congress, GAO B-175425, April 17, 1972; Government Accountability Office. (1992). Prescription Drug Monitoring – States Can Readily Identify Illegal Sales and Use of Controlled Substances. Washington, D.C., Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/HRD-92-115, July 1992.

²⁴ Government Accountability Office. (1992). Medicaid Prescription Drug Diversion – A Major Problem, But State Approaches Offer Some Promise. Washington, D.C., Testimony Before Select Committee on Narcotics Abuse and Control, House of Representatives, GAO/T-HRD-92-48, July 29, 1992; Government Accountability Office. (1992). Prescription Drug Monitoring – States Can Readily Identify Illegal Sales and Use of Controlled Substances. Washington, D.C., Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/HRD-92-115, July 1992.

²⁶ U.S. Customs and Border Protection, Canada Border Services Agency, & Royal Canadian Mounted Police. (2010). United States - Canada: Joint Threat and Risk Assessment https://www.dhs.gov/xlibrary/assets/uscanada-jbtra.pdf.

²⁷ Valdez, A., Cepeda, A., Kaplan, C. D., & Yin, Z. (1998). The Legal Importation of Prescription Drugs into the United States from Mexico: A Study of Customs Declaration Forms. *Substance Use & Misuse*, 33(12), 2485-2497.

distributor in Mexico City.²⁸ Similarly, increased smuggling of OxyContin from Canada was reported in 2001 and believed to be smuggled via the St. Croix River and the Calais, Maine, port of entry.²⁹ In response to the increased diversion of prescription opioids, Purdue Pharma, the manufacturer of OxyContin, developed unique markings for OxyContin tablets intended for sale in Mexico and Canada to assist law enforcement in identifying diverted prescription drugs smuggled into the United States.³⁰

Uncontrolled Internet Sales

Scheduled prescription drugs may also be obtained through Internet sites advertising sale of prescription drugs with few or no prescription controls. In a study by Beau Dietl & Associates (BDA) for the Center for Addiction and Substance Abuse at Columbia University, researchers searched for all Internet sites offering prescription drugs during a one-week period in January 2004, and identified a total of 495 web sites offering Schedules II, III, IV, and V controlled prescription drugs.³¹ Seventy-three percent were Schedules II and III and of those 41% were Schedule II drugs. The study found that 99% of the internet sites did not require any prescription; 41% stated that no prescription was needed and 49% offered an "online consultation." Four percent required that a prescription be faxed, 2% required that a prescription be mailed, and 4% made no mention of the need for prescriptions.

The report pointed out that many of the Internet pharmacy sites appeared and disappeared rapidly. Computer technology allows web sites to be put up, moved, or be taken down in a short period of time, which makes it difficult for regulators to investigate, monitor or shut down illegal sites. In a similar study, a team from the GAO sought to assess the extent to which certain prescription drugs could be purchased over the Internet without a prescription.³² It placed up to ten orders for 13 selected prescription drugs from different online pharmacies. For all 13 selected drugs, a total of 90 orders were placed, 68 of which were actually delivered. Forty-five of these were obtained without providing a prescription. In an effort to address this issue, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 amended the CSA to add online pharmacies as another controlled substance handler subject to the same level of monitoring by the DEA, including the requirement to register.³³ Recent results from the NSDUH report that less than

³¹ National Center on Addiction and Substance Abuse at Columbia University. (2004). You've Got Drugs! Prescription Drug Pushers on the Internet. New York, NY, Background research provided by Beau Dietl & Associates, CASA White Paper, February 2004.

³² Government Accountability Office. (2004). Internet Pharmacies – Some Pose Safety Risks for Consumers. Washington, D.C., Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate, GAO-04-820.

²⁸ Drug Enforcement Administration. (2003). Country Profile for 2003: Mexico https://www.ncjrs.gov/pdffiles1/203745.pdf. United States Department of Justice: National Criminal Justice Reference Service.

²⁹ Solicitor General (2001). United States–Canada Border Drug Threat Assessment. *National Drug Intelligence Center*. Johnstown, PA., Product No. 2002-RO243-001.

³⁰ Government Accountability Office. (2004). Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem. Report to Congressional Requesters <u>http://www.gao.gov/htext/d04110.html</u>.

³³ More specifically, the law requires that controlled substances may not be dispensed through the internet without a valid prescription by a physician that has conducted at least one in-person medical exam. "Controlled Substances Act," 21 USC Section 801. Available at <u>http://www.gpo.gov/fdsys/pkg/PLAW-110publ425/pdf/PLAW-110publ425.pdf</u>. Retrieved on February 10, 2015.

one percent of persons 12 and older reported purchasing the prescription drugs used most recently from the Internet.³⁴

At present, we are unable to gauge the relative contribution of these different channels to the illicit market. Amounts diverted through thefts and reported losses are tracked by DEA, and recent studies by Abt provide an estimate of the amounts of opioids and benzodiazepines diverted by doctor shoppers, but the size of the total illicit market is unknown.³⁵ All of these diversion channels can be used by individuals, by groups of individuals, or by Drug Trafficking Organizations (DTOs). The persons involved may include leaders, financiers, 'patients,' permissive or corrupt prescribers and dispensers, or distributors.

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³⁴ Substance Abuse and Mental Health Services Administration. (2014). Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD.

³⁵ McDonald, D. C., & Carlson, K. E. (2013). Estimating the prevalence of opioid diversion by "doctor shoppers" in the United States. *PLoS One*, 8(7), e69241; McDonald, D. C., & Carlson, K. E. (2014). The ecology of prescription opioid abuse in the USA: geographic variation in patients' use of multiple prescribers ("doctor shopping"). *Pharmacoepidemiology and Drug Safety*, 23(12), 1258-1267.

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National Response

The prescription drug abuse epidemic has been the subject of congressional hearings,³⁶ public health grand rounds hosted by the Centers for Disease Control and Prevention, ³⁷and the subject of a targeted action plan released as a supplement to the National Drug Control Strategy.³⁸ It has also been raised as a significant public safety threat among state and local law enforcement. A national survey of law enforcement agencies found that the number of agencies reporting controlled prescription drugs as the most significant threat to their community increased by more than ten percent between 2009 and 2014, with over 90 percent gauging availability of controlled prescription drugs to be a moderate to high threat in their community.³⁹

There is also growing concern with the link between opioid and heroin use, which is supported by increasing evidence that non-medical use of controlled prescription opioids is a risk factor for future heroin use. Using pooled data from the NSDUH from 2002 through 2011, Muhuri and colleagues found that recent heroin use was 19 times higher among those who reported prior non-medical use of pain relievers than those who did not. This research also found that four out of five respondents reporting first time heroin use in the past 12 months reported prior non-medical use of pain relievers.⁴⁰ These findings are supported by targeted ethnographic studies, which were able to attribute the progression to a combination of increased availability of heroin and its comparatively lower cost.⁴¹ One study also found that among thirty-one current heroin injectors in two major U.S. cities, younger heroin injectors were

³⁶ Manchikanti, L. (2006). Prescription drug abuse: what is being done to address this new drug epidemic? Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. *Pain Physician*, 9(4), 287-321.

³⁷ Paulozzi, L., Baldwin, G., Franklin G., Kerlikowske, R.G., Jones, C.H., Ghiya, N., and Popovic, T. (2012). CDC grand rounds: prescription drug overdoses – a U.S. epidemic. *Morbidity and Mortality Weekly Report*, 61(01), 10-13.

³⁸ White House. (2011). Epidemic: Responding to America's Prescription Drug Abuse Crisis <u>http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf.</u> Retrieved February 6, 2015.

³⁹ Drug Enforcement Administration. (2014). National Drug Threat Assessment Summary 2014 https://info.publicintelligence.net/DEA-DrugThreats-2014.pdf. United States Department of Justice. Accessed February 6, 2015.

⁴⁰ Muhuri, P. K., Gfroerer, J. C., & Davies, M. C. (2013). Associations of nonmedical pain reliever use and initiation of heroin use in the United States. *The Center for Behavioral Health Statistics and Quality Data Review*.

⁴¹ Daniulaityte, R., Carlson, R. G., & Kenne, D. R. (2006). Initiation to Pharmaceutical Opioids and Patterns of Misuse: Preliminary Qualitative Findings Obtained by the Ohio Substance Abuse Monitoring Network. *Journal of Drug Issues, 4 (36)*, 787-808; Inciardi, J. A., Surratt, H. L., Cicero, T. J., & Beard, R. A. (2009). Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultrarapid Assessment. *Pain Medicine, 10*(3), 537-548; Siegal, H. A., Carlson, R. G., Kenne, D. R., & Swora, M. G. (2003). Probable relationship between opioid abuse and heroin use. *American Family Physician, 67*(5), 942-945; Grau, L. E., Dasgupta, N., Harvey, A. P., Irwin, K., Givens, A., Heimer, R., & Kinzly, M. L. (2007). Illicit use of opioids: Is OxyContin® a "gateway drug"? *American Journal on Addictions, 16*(3), 166-173.

more likely to have moved to heroin after opioid use than the older heroin injectors, suggesting that the progression from heroin to opioids may be particular to younger populations.⁴²

In 2011, in response to the growing evidence of the scale of non-medical use of prescription drugs, the President's National Drug Control Strategy included a plan for reducing prescription drug use, entitling it, *"Epidemic: Responding to America's Prescription Drug Abuse Crises."* The plan called for action in four areas:

- The first area is in *raising awareness through education* of healthcare providers, patients, parents, and youth. This includes educating parents on the risks of prescription drug misuse, debunking the myth among youths that prescription drugs are less dangerous than illegal drugs, and educating health care providers on appropriate prescribing practices and signs of substance abuse.
- The second area is in *tracking and monitoring prescription drugs* through prescription monitoring programs (PDMPs) to detect and prevent diversion at the retail level.
- The third area is to provide convenient and environmentally-safe legal options for *disposal of medications*.
- The fourth area is in the detecting and preventing practitioners and patients and non-patients involved in the diversion of prescription drugs through *targeted enforcement activities*.⁴³

The plan also highlighted the unique nature of these drugs: controlled prescription drugs are not inherently illegal, one can obtain them legitimately, and legitimate actors in the medical community have a role in making the drug available. Contrast this to heroin or cocaine, which is illegally manufactured, distributed, and used. In the case of illegal use of controlled prescription drugs, the prevention responses are broader and include both practitioners and patients and non-patients.

In this report, we focus on how ONDCP, through the High Intensity Drug Trafficking Areas (HIDTA) Program, has supported action in three of the four action areas identified in the National Drug Control Strategy, highlighting specific initiatives implemented in the three HIDTA regions targeted for this study, where appropriate. Then we cover the fourth action area, PDMPs, highlighting programs in the three targeted HIDTA regions and their potential for preventing and detecting prescription drug diversion.

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⁴² Mars, S. G., Bourgois, P., Karandinos, G., Montero, F., & Ciccarone, D. (2014). Every 'Never' I Ever Said Came True: Transitions from opioid pills to heroin injecting. *International Journal of Drug Policy*, 25(2), 257-266.

 ⁴³ White House. (2011). Epidemic: Responding to America's Prescription Drug Abuse Crisis <u>http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf.</u> Retrieved February 6, 2015.

High Intensity Drug Trafficking Areas (HIDTA) Program

The HIDTA program, funded by ONDCP, was established through the Anti-Drug Abuse Act of 1988 and provides federal resources to support multi-agency coalitions that operate at the regional level around a shared mission to address the drug trafficking problem and its harmful impacts in its area. ⁴⁴ The elements of the program that make it particularly effective for implementing the President's plan includes its emphasis on multi-agency and multi-disciplinary cooperation, as well as its flexibility to support local decision making regarding how best to address regional drug threats.

Since the program's authorization, ONDCP has designated 28 regions across the country as HIDTA regions. To meet statutory requirements, HIDTAs must provide an assessment of the drug threat to the region and its harmful consequences, the current investment of law enforcement resources, and the need for additional federal resources to appropriately address the threat. Each HIDTA is comprised of multiple counties, and in some cases, multiple states that meet statutory requirements to be designated as part of a HIDTA region.

Regardless of the size of the HIDTA, all are required to adhere to the goals of the national program, which are to reduce drug trafficking and drug production by:

- facilitating cooperation among Federal, state, local, and tribal law enforcement agencies to share information and implement coordinated enforcement activities;
- enhancing law enforcement intelligence sharing among Federal, state, local, and tribal law enforcement agencies;
- providing reliable law enforcement intelligence to law enforcement agencies needed to design effective enforcement strategies and operations; and
- supporting coordinated law enforcement strategies which maximize use of available resources to reduce the supply of illegal drugs in designated areas and in the United States as a whole.⁴⁵

All HIDTAs share a common structure. Each HIDTA functions as a multi-agency coalition overseen by an Executive Board comprised of an equal number of executives from each Federal and non-Federal (state, local, or tribal) law enforcement agency participating in the HIDTA. The Executive Board is responsible for determining how federal funds are directed to support the HIDTA program mission and the specific drug threats in the region. The Executive Board determines how federal funds may be used to support the following four different types of initiatives:

- Management and Coordination initiatives support the basic overhead of the HIDTA;
- *Intelligence and Information Sharing initiatives* provide intelligence analysis, deconfliction services, information collection and dissemination, and other analytical support;

⁴⁴ Office of National Drug Control Policy, Executive Office of the President. (June 2011). Fact Sheet: High Intensity Drug Trafficking Areas (HIDTA) Program <u>http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/hidta_fact_sheet_6-14-2011.pdf</u>. Retrieved on April 30, 2009.

 ⁴⁵ Section 301 of the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109-469;
 21 U.S.C. 1701 et seq.)

- *Support initiatives* support enforcement and intelligence efforts through training, prevention and treatment, and information technology; and
- *Enforcement initiatives* focus on investigation, interdiction, fugitive apprehension, or prosecution activities associated with drug trafficking and other related major crime.

The Executive Board is responsible for determining how federal funds should be aligned across initiatives to support the HIDTA program mission and the specific drug threats in the region. These decisions are supported by a regional threat assessment, which ONDCP requires that each HIDTA conduct on an annual basis. The threat assessment typically starts with an overview of the top drug threats and then provides detailed information on the types of drugs being manufactured, cultivated, imported, distributed, or diverted into and through the regions, the organizations involved, transportation routes, methods, and money laundering and bulk cash smuggling activity. The findings from the threat assessment are used to inform the HIDTA's annual strategy and budget.

The HIDTA program is awarded over \$200M each year. HIDTAs are funded on an annual basis and must provide a budget request and strategy in support of that request. In addition to base funding, individual HIDTAs may apply for discretionary funding that is made available through ONDCP to address emerging drug trends such as prescription drug or heroin abuse. For example, the New England HIDTA received funding in 2011 which was allocated to the Southern New Hampshire Task Force Initiative to start a Prescription Drug Project that would be dedicated to controlled prescription drug diversion investigations involving opioids (e.g., oxycodone, hydrocodone, OxyContin). It also received funding in 2013, which it provided to the Boston University School of Medicine to support practitioner education programs and to the Southern New Hampshire Task Force to support its Prescription Drug Project. The New Mexico HIDTA received discretionary funding in 2011 and in 2012, which it provided to the DEA-led HIDTA task forces to support the national drug take-back program.

While all of the HIDTAs are linked by these common goals, structure, and funding stream, the program is supported by decision making through the Executive Board, which is represented by federal, state and local membership, all of who have an equal vote in how funding is allocated. Therefore, the program's success relies on the ability of the agencies within designated HIDTA regions to identify existing and emerging drug threats and to tailor a coordinated strategy to reduce or eliminate the production, manufacture, distribution, and use of illegal drugs. As stated above, the Executive Board is responsible for holding initiatives accountable to their goals, which may include specific responses to emerging threats, like prescription drug abuse. For example, the HIDTA may provide training on investigating prescription drug diversion that is available to all law enforcement agencies in its region, expand a task force's mission to include targeting DTOs involved in prescription drug diversion, or provide funding to a prevention or education program targeting prescription drug diversion or abuse.

In the next sections, we describe the different types of initiatives and how they may support the HIDTA's response to the prescription drug diversion threat, providing specific examples from the HIDTAs targeted for this study where relevant.

Intelligence and Information Sharing Initiative

The sharing of intelligence and information across federal, state, and local law enforcement agencies is part of the basic philosophy underlying the HIDTA program. Therefore, each HIDTA is required to have at least one intelligence and information sharing initiative that is responsible for collecting, analyzing, and disseminating law enforcement information and intelligence for the HIDTA.

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HIDTA program guidelines suggest that each HIDTA provide a single primary intelligence center, staffed with commingled participants from federal and state/local agencies. The involvement of multiple agencies is designed to promote on-site access to multiple intelligence systems to support core information sharing functions. The core intelligence functions include deconfliction, analytical case support, and developing and disseminating intelligence products.

It is through the development and dissemination of strategic intelligence products that the intelligence initiative can support law enforcement agencies in their efforts to target prescription drug diversion. As reflected above, each HIDTA is tasked with generating an annual threat assessment, which provides an analysis of the regional drug threats, to include, for example, information on the types of drugs trafficked, the organizations involved in the manufacture, trafficking, distribution of illicit drugs, transportation routes, illicit finance, and emerging drug threats, which may include prescription drug diversion. The annual threat assessment serves as a resource for law enforcement agencies in the region to obtain information on the drug threats specific to the region and to identify emerging or new threats. While the annual threat assessment was conducted by the National Drug Intelligence Center (NDIC) for some HIDTAs in the past, these assessments are currently being conducted by all HIDTA's intelligence and information sharing initiatives. Many HIDTAs supplement the threat assessments with additional tactical and strategic intelligence products throughout the year for law enforcement agencies in the region, some of which may be targeted to a particular drug threat. For example, in 2010, the Houston HIDTA developed a document entitled, "Overview of Pharmaceutical Abuse and Diversion: A Growing Threat to the Houston HIDTA." The document provided an overview of prescription drug abuse, diversion techniques, geographical variance in diversion techniques, and efforts to combat pharmaceutical diversion, to include past and present legislation.⁴⁶

A mix of federal, state, and local analysts assigned to HIDTA intelligence centers also provide case support to agents and task force officers. Analysts typically have access to a range of information systems, including Narcotics and Dangerous Drugs Information System (NADDIS), Financial Crimes Enforcement Network (FinCEN), Treasury Enforcement Communications System (TECS), Nationwide Bureau of Motor Vehicles, National Law Enforcement Telecommunications System (NLETS), LexisNexis, and various state and local law enforcement databases. In addition to basic database checks (e.g., criminal histories), analysts also support investigators with more complex activities, including, but not limited to, pen link charts, telephone toll analysis, wire intercept support, and assistance obtaining subpoenas or search warrants.

For the most part, the same resources used to support traditional investigations may be used to support prescription drug diversion investigations. However, analysts may have access to additional resources specific to diversion investigations. For example, analysts at the New Mexico HIDTA ISC have direct access to the New Mexico PDMP and may use it to submit queries to obtain information for prescriptions filled for specific patients during a specified time frame.

⁴⁶ Houston HIDTA Intelligence Support Center. (July 2010). "Overview of Pharmaceutical Abuse & Diversion: A Growing Threat to the Houston HIDTA." <u>https://info.publicintelligence.net/HoustonHIDTA-Pills.pdf</u>. Retrieved February 26, 2015.

Support Initiatives

The HIDTA program is designed to improve the effectiveness and efficiency of HIDTA operations. In support of this goal, HIDTAs may fund any number of support initiatives to include training, prevention, information technology, and, in some cases, treatment.

Training

Each HIDTA is required to establish a training initiative and to designate a training coordinator to assess training needs, coordinate and facilitate training activities, liaison with training components in law enforcement agencies within the HIDTA region, and document and report on all training activities. In most cases, and in the case of the three targeted HIDTAs, the HIDTA has designated one person to serve as the Training Coordinator for the HIDTA. That person is responsible for identifying courses that would be of interest not just to analysts, task force officers, and federal agents participating in the HIDTA, but to representatives from all law enforcement agencies in the region. Examples of training courses include clandestine lab certification, parcel interdiction, narcotics investigations, interview and interrogation, financial investigations, Mexican drug cartels, and asset forfeiture investigations.

Once identified, the Training Coordinator coordinates with the training provider on dates and advertises the class through either a training tab on the HIDTA's website or through email to representatives from the enforcement or intelligence community in the region.

While prescription drug diversion may be covered in basic narcotics training programs, diversion investigators benefit from training on the different types of drugs, effects of these drugs, and laws that are relevant to diversion investigations. In 2014, regional HIDTA programs sponsored 59 training courses that address the diversion and abuse of opiates.

One of the training courses the HIDTA can sponsor in response to the prescription diversion threat is a training on Prescription Drug Crimes, which is sponsored by Purdue Pharma L.P. – RxMatters.org. This course, which has been sponsored by a number of HIDTAs, including the New England HIDTA in 2013 and again in 2014, covers prescription drug identification and trends, lawful prescribing, abuse and diversion, a major case study, and RxPatrol (an intelligence database maintained by Purdue Pharma to track pharmacy robberies, burglaries, and thefts related to controlled substances).⁴⁷ HIDTAs have also received training from the Public Safety Alliance LLC through a course entitled, "Dealing Death: Trafficking Prescription Pills," which explains how prescription pills are diverted, distributed, and used⁴⁸, and the National Law Enforcement Speakers Bureau through a course entitled, "Prescription Drug Investigations," which provides an overview of prescription drugs, diversion methods, and how conspiracy laws may be applied to these types of investigations.⁴⁹

⁴⁷ For more information, see <u>http://www.rxsafetymatters.org/law-enforcement-and-government/education-and-resources/</u>. Retrieved on February 26, 2015.

⁴⁸ For more information, see <u>http://trainpsa.org/default.aspx/MenuItemID/117/MenuSubID/2/MenuGroup/Our+Services.htm</u>. Retrieved on March 24, 2015.

⁴⁹ For more information, see <u>http://nationallawenforcementspeakersbureau.com/Classes.html</u>. Retrieved on February 26, 2015.

HIDTAs may also provide funds to support educational opportunities provided at conferences targeted to law enforcement, for example, the annual conference hosted by the HIDTA's National Methamphetamine and Pharmaceuticals Initiative (NMPI) and the National and Regional Rx Drug Abuse Summits.

Prevention

HIDTAs may provide funds to support an existing community-based prevention program. For example, the New England HIDTA, through supplemental funding, provides funds to a local Sheriff's office to support a leadership camp for at-risk youth ages 8-14 years old that includes an anti-drug prevention programming element. The HIDTAs may also provide funds to establish new prevention programs. For example, the New Mexico HIDTA provided funds to the city of Espanola in 2014 to support establishing an anti-drug program targeting at-risk youth named Project RACE (Rio Arriba County Empowerment). Program participants sign a pact with their school to remain drug free and participate in job training one day a week and community service activity one weekend a month to be eligible for jobs in the community (through local businesses) that pay \$1 more than minimum wage.

The Northwest HIDTA's prevention initiative is much broader than these other two examples, involving 20 different partners that support its four core projects, which include community coalition support, drug

court development, public education and awareness, and management information systems and evaluation. While many of the partners support demand reduction and prevention programming and provide and disseminate information resources to support public education efforts that cover illicit drug use more broadly, two partners have implemented programs specific to the misuse of prescription drugs. The Greater Spokane Substance Abuse Council (GSSAC), a community coalition comprised of community agencies, policy makers, and citizens from the greater Spokane region distribute a "Rx Watch" publication and has designed a community education course with the goal of educating the community on the dangers of prescription drug abuse. The course covers the history of opiate use and how prescription opiate abuse is driving first-time heroin use in Washington, how to identify the

Long-term opioid therapy for non-cancer patients became the preferred pain management tool for many physicians in the 1990s for several key reasons:

- Increased understanding of chronic pain as an overall threat to health.
- Evolving consensus on treatment of neuropathic and other pain with long term opioid medications.
- Availability of powerful new opioid analgesics to treat pain, and
- Aggressive marketing of these drugs to patients and physicians.

signs of prescription drug abuse, how to identify prescription drug paraphernalia, and ways to secure prescription drugs in the home. The course is free and the GSSAC also provides a free train-the-trainer course for individuals to become certified presenters. Thurston Together is another community coalition that, in addition to overseeing five prescription drug take back boxes in the county, has, in partnership with the Washington Association for Substance Abuse and Violence Prevention and the Partnership for Drug-Free Kids, ran a state-level pilot of the "Rx360" program, which it offers community groups, concerned citizens, and parents on a fee-for-service basis. Similar to Rx Watch, Rx360 pulls health, prevention, and treatment professionals from the area together to present information about the prevention of prescription drug abuse.

Education

Education is one of the key tools law enforcement has to achieve prevention goals. For practitioners treating patients with chronic pain, choosing long-term opioid therapy means balancing the benefits of pain management against the risks of addiction, misuse, and overdose. Guidance for physicians is crucial

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for opioid prescribing because there is enormous variation in prescribing practices, in part due to changing consensus on the ideal treatment for chronic pain over the past several decades. The Federation of State Medical Boards promulgated model guidelines in 1998 that authorized flexibility in pain management, including more expansive use of opioids,⁵⁰ which was reinforced by policy statements in 2004,⁵¹ although some noted that medical boards in several states were slow to revise their policies.⁵² To promote more expansive treatment of pain in hospitals, the Joint Commission on the Accreditation of

Healthcare Organizations proposed in 2001 that pain be considered the "fifth vital sign"⁵³ and others argued that the under-treatment of pain constituted a "prominent public health concern."⁵⁴ These developments led to a new consensus that opioid therapy is appropriate for some patients with chronic non-cancer pain. This change in thought coincided with availability of new and powerful drugs which were marketed aggressively by their manufacturers.⁵⁵

More recently, reviews of literature on long-term opioid therapy have shown little evidence of the effectiveness of the treatment, but have shown serious risks of opioid dependence, abuse, overdose, and other adverse health effects.⁵⁶ These risks, coupled with the presumed connection between high rates of opioid abuse and increases in heroin use have led many to call for action to prevent prescription opioid abuse and dependence that include prescriber education.

"There is a growing acknowledgement...that we can't arrest way out of the [drug] problem: people need care, intervention and treatment. A drug user's first interaction with the system is often with law enforcement so we need to ensure they are getting prevention and intervention strategies along the way. We need to ensure that people with substance use disorders get treatment. We also need to prevent prescription drug abuse in the first place, which is why we are here now." **ONDCP** Director Botticelli opening remarks at Scope of Pain Conference, May 2014

⁵⁰ Federation of State Medical Boards of the United States Inc. (1998). Model Guidelines for the Use of Controlled Substances for the Treatment of Pain <u>http://www.nsmadocs.org/pdf/ModelGuidelines.pdf</u>. Euless, Texas 1998.

⁵¹ Federation of State Medical Boards of the United States Inc. (2004). Model Policy for the Use of Controlled Substances for the Treatment of Pain <u>http://mn.gov/health-licensing-</u> <u>boards/images/2004_grpol_Controlled_Substances.pdf</u>. Euless, Texas 2004.

⁵² Joranson, D. E., Gilson, A. M., Dahl, J. L., & Haddox, J. D. (2002). Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change. *Journal of Pain and Symptom Management*, 23(2), 138-147.

⁵³ As cited in Lucas, C. E., Vlahos, A. L., & Ledgerwood, A. M. (2007). Kindness Kills: The Negative Impact of Pain as the Fifth Vital Sign. *Journal of the American College of Surgeons*, 205(1), 101-107. doi: <u>http://dx.doi.org/10.1016/j.jamcollsurg.2007.01.062</u>

⁵⁴ Fishman, S. M., Papazian, J. S., Gonzalez, S., Riches, P. S., & Gilson, A. (2004). Regulating opioid prescribing through prescription monitoring programs: balancing drug diversion and treatment of pain. *Pain Medicine*, 5(3), 309-324.

⁵⁵ Van Zee, A. (2009). The promotion and marketing of oxycontin: commercial triumph, public health tragedy. *American Journal of Public Health*, *99*(2), 221-227.

⁵⁶ Chou, R., Deyo, R., Devine, B., Hansen, R., Sullivan, S., Jarvik, J. G., . . . Turner, J. (2014). The effectiveness and risks of long-term opioid treatment of chronic pain. *Vol Evidence Report/Technology Assessment No. 218*. Rockville, MD: Agency for Healthcare Research and Quality.

In 2012, the FDA required manufacturers to comply with a risk evaluation and mitigation strategy (REMS) for extended-release and long-acting opiates.⁵⁷ Manufacturers were required to pool funds and develop practitioner education programs. The REMS companies provided grant support to develop the materials presented at the Scope of Pain conference along with others.

The New England HIDTA began providing supplemental HIDTA funds to the Boston University School of Medicine in support of the Scope of Pain conferences in 2013. The Scope of Pain conference is intended to provide guidance to practicing physicians on long-term opioid prescribing to help mitigate the risks, while maintaining access to medication for patients who need it.

Below we provide a description of a Scope of Pain conference that was conducted in Portsmouth, New Hampshire on May 2014 and co-sponsored by the New England HIDTA.⁵⁸

The conference agenda included opening remarks by Colonel Robert Quinn of the New Hampshire State Police, ONDCP Director Michael Botticelli, and course director Dr. Daniel Alford. Each speaker emphasized the impetus for the conference: the burgeoning problem with heroin dependence and abuse, and the contribution opioid overuse and abuse plays in narcotic addiction. Each speaker also emphasized the role physicians can play in mitigating overuse of opiates to manage chronic pain and reduce availability of opioid medications.

The rest of the conference addressed the three distinct conference sponsors and constituencies: law enforcement, prevention and public health, and the current regulatory and resource environment.

- The law enforcement session highlighted the link between prescription opiate use and progression to heroin addiction, resources that are newly available via Medicaid expansion for addiction treatment, and that partnerships such as the one that produced the Scope of Pain conference should be able to leverage these resources to begin to address the problem of prescription opioid misuse.
- The clinical practice session addressed assessing pain and opioid misuse and risk; initiating opioid therapy safely; assessing and managing aberrant medication taking behavior; and included a question and answer/clinical interaction demonstrations.
- The final session was a resource and regulatory panel discussion comprised of representatives from the Massachusetts Department of Public Health, DEA, New Hampshire State Police, and Northern New England Poison Center to describe agency resources available to help address the prescription drug diversion problem.

Enforcement Initiatives

HIDTA Enforcement initiatives investigate, interdict, and prosecute organizations involved in drug trafficking or other related major crimes. All enforcement initiatives are expected to include multi-agency participation (i.e., full-time federal and state or local agency personnel) and be collocated and

⁵⁷ Food and Drug Administration. (2015). Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids. <u>http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.</u> Retrieved on March 7, 2015.

⁵⁸ Other Scope of Pain conferences cover similar topics, but may use different speakers.

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commingled. Collocated means working in the same facility and commingled means all initiative participants have access to and interact with each other.

As discussed earlier, HIDTAs support a number of enforcement initiatives, each with its own composition and directive. Enforcement initiatives may be comprised of a single or multiple enforcement groups or task forces. As a result, enforcement initiatives vary in size from task forces staffed with a dozen or fewer task force officers or agents to some with over one hundred task force officers/agents. Initiatives also differ in their focus, e.g., investigative, interdiction, as well as in their targets, e.g., a specific type of illegal drug (methamphetamine, prescription drug diversion) or organization (e.g., gangs). Initiatives may also differ in the types of agencies (federal versus non-federal) leading the initiative and the balance of federal and non-federal representatives serving on the task force.

HIDTA funding is never the only funding source supporting an initiative. HIDTA funds may be used, for example, to pay the salary or overtime to state or local task force officers, to pay informants and purchase evidence, or to rent vehicles. Other direct and indirect sources include federal, state, or local agency funds and, for example, asset forfeiture, grants (e.g., Bureau of Justice Assistant's Justice Assistance Grant (JAG) Program), and the Organized Crime Drug Enforcement Task Force (OCDETF)).

Federally and Non-Federally led Enforcement Initiatives

All enforcement initiatives are required to have both federal and non-federal participation to receive HIDTA funds. This may mean that a local task force gains one or more federal agents or that a federal task force gains one or more task force officers. Whether a task force is led by a federal or non-federal agency can have a number of implications for the types of cases investigated by the task force.

Non-federally led task forces. Some HIDTA task forces are led by state, local, or tribal law enforcement agencies and may function as the narcotics unit for the participating agencies. This means that the task force investigates mid-level dealers supplying retail-level dealers in the area. Investigations by these task forces tend to be initiated through intelligence shared by officers assigned to their home agency or through informants. Traditional investigation strategies are applied (i.e., surveillance, trash pulls, buy/busts, arrestee debriefing) to gather sufficient evidence to charge drug traffickers with state charges.

The addition of federal agents to these task forces brings the resources and expertise to, when possible, pursue higher levels of the drug trafficking network and prosecute them in federal court. Depending on the investigation, this may be pursued independently by the task force or as part of a joint investigation with the federal agent's home agency.

Federally-led task forces. Other HIDTA task forces are led by federal agencies, including the DEA, Federal Bureau of Investigations (FBI), Homeland Security Investigations (HSI), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), and to a lesser extent the U.S. Postal Service. In most cases, the HIDTA program serves to supplement existing federal enforcement groups with one or more nonfederal task force officer, who are deputized as a federal agent to have the same authority as their federal counterparts in the task force. While the types of investigations generated by these groups may be influenced by the federal agency's directive (controlled substances, violent crimes, money laundering, bulk cash smuggling, or federal offenses involving firearms), the goal of all investigations is to pursue high-level criminal organizations.

Federal leadership brings both the resources and the authority to expand investigations in both scope and geography. Federal investigations are often long term, requiring more manpower and resources to, for example, pay informants for information, purchase increasingly larger quantities of drugs that enable

investigators to move up the supply chain, travel to other regions of the country to conduct controlled deliveries, and identify associates through state and federal wiretaps.

The agency leading the task force can be particularly relevant for prescription drug diversion investigations, especially when practitioners are involved in the diversion.

Diversion Investigations

Diversion investigations may range in (1) the size and scale, from an individual doctor shopper to multiple individuals hired to fill prescriptions in return for pills, and (2) in sophistication of the operation, from forging a single prescription to hiring and transporting a group of individuals out of state to engage in doctor shopping. For many investigations, the task force's approach is similar to investigations involving other illegal drugs, the goal being to identify the leader organizing the operation, someone financing the operation, a connection to sources of supply and distributors, and people moving loads from one point to another or to divert pills at one location and transport them to another location. Investigations typically start with lower level participants that have been caught, have knowledge of the organization, and are willing to share that information or with an informant who can make introductions to individuals with knowledge of the organization. The next step is to try to identify co-conspirators, particularly those higher up the chain of command, and build evidence using a range of methods including debriefings, trash pulls, surveillance, trackers, pen registers, and wire taps. When investigators decide in conjunction with prosecutors that enough evidence has been generated, they move to disrupt (e.g., seizures or arrests) and/or dismantle the criminal organization (e.g., indictments of all key members).

Where investigations of prescription drug diversion are likely to differ from investigations of illegal drug trafficking is in the specialized knowledge (e.g., laws and regulations governing the prescribing and dispensing of prescription drugs, the ability to identify inappropriate prescribing behavior), intelligence (prescribing practices), and expertise necessary to investigate and prosecute (administratively and/or criminally) individuals and groups diverting drug using different channels (e.g., doctor shopping, prescription fraud, Internet purchases, theft).

For this report, attempts to learn about these differences is limited to non-federally led HIDTA task forces whose diversion investigations involved patient-centered diversion because of concerns among federal agencies about the public nature of the report.

Diversion Investigations by Non-Federally-led Task Forces. In three non-federal task force participating in the New Mexico HIDTA,⁵⁹ supervisors confirmed that most of its diversion cases are not DTOs, rather they involve a patient selling some of their prescribed pills or single non-patients obtaining pills through fraud or doctor shopping. They pursue these cases primarily through traditional investigative work (buy/bust, surveillance), but may use handwriting analysis, for example, in a prescription forgery case, as well as an online database called "Leads on Labs."⁶⁰ One task force worked with prescribers to shift to electronic prescriptions to address use of stolen prescription pads.⁶¹ These false patients are identified,

⁵⁹ The three New Mexico HIDTA task forces that participated included the Region II, Region III, and Regional Interagency Drug Task Force.

⁶⁰ Leads on Labs is an online database that is administered by a private company and sends emails regarding suspicious activity, based on information voluntarily submitted by pharmacies.

⁶¹ Interview Notes Region II Task Force, June 2014.

most frequently by pharmacies, and in other cases by practitioners (doctors or nurses) when their employees may be involved.

In all cases, task forces reported the importance of establishing good relationships with practitioners and pharmacies to identify investigative targets, which also helps to build trust. While these efforts help address diversion through doctor shopping and fraud, task forces are also dealing with individuals using the mail to receive bulk shipments of diverted pills, like the case described below.

The case was initiated from a tip received from a FedEx delivery person who saw a broken box containing OxyContin pills. FedEx also confirmed that multiple packages had been shipped between the local address and another address in Arizona over the past three months. While the task force was arranging for a controlled delivery, it received a call from law enforcement in Arizona, confirming that the person in Arizona was supplying the local dealer and also sharing that the person in Arizona was obtaining the pills from someone working in a doctor's office. Through surveillance and traffic stops, the task force was able to confirm that the local dealer was distributing pills out of his house and to identify individuals working for him. Unfortunately, the dealer moved operations before an arrest could be made; the investigation suspected the something had caused the dealer to become suspicious.

The three New Mexico HIDTA task force supervisors reported that prescription drug cases can be challenging because it is difficult to have cases accepted for prosecution unless the individual is in possession of a large quantity of pills, is in possession of other illegal drugs, or has no legitimate prescription. This is problematic because PDMP reporting was not required until 2012. In other words, because there is some reluctance to put users in jail, prosecutors are looking for confirmation that individuals are dealing pills. To address this issue, one task force supervisor serves as a consultant to the local drug court program to help distinguish users from dealers.⁶²

All three task forces also confirmed that they often do not have the resources or authority to pursue long term cases that involve practitioners or pharmacies and will refer these cases to the DEA diversion unit. One task force reported that another reason for referring the case is that federal charges bring longer sentences than state charges. This preference to pursue diversion cases federally was reinforced by statements by the New Mexico HIDTA Director noting the complicated nature of these types of investigations and how they often become an expensive "battle of the experts" (referring to the need to hire one doctor to validate concerns with the prescribing practice of another doctor).⁶³

While two of the three New Mexico task forces included in the study refer all prescription drug cases that involve pharmacies or practitioners to the DEA, the third task force established its own diversion unit in 2010 staffed with one diversion investigator. The investigator has been authorized to have direct access to the state PDMP and, rather than referring cases to DEA, works jointly with the DEA diversion unit on cases involving practitioners or pharmacies.

Two non-federal task forces participating in the Northwest HIDTA reported similar protocols.⁶⁴ When prescription drug diversion investigations uncovered substantial prescription drug trafficking

⁶² Interview Notes Region II HIDTA Task Force, June 2014.

⁶³ Interview Notes New Mexico HIDTA Director, June 16, 2014.

⁶⁴ The two Northwest HIDTA task forces participating in the research included the Snohomish Regional Drug Task Force and the Thurston County Narcotics Task Force.

conspiracies, such as pill mills or prescription fraud rings, the case would be referred to the DEA Tactical Diversion Squad for further investigation.

The rationale for referral to one specialized task force is that investigating pharmaceutical trafficking requires specialized surveillance, investigation, and analytic skills. For example, prescription drug diversion task forces develop relationships with pharmacies and educate them about signs of suspicious activity (e.g., numerous customers filling prescriptions for the same drug type from the same doctor issued the same day; how to recognize counterfeit prescriptions) and providing contacts for reporting illegal or suspicious activity. Specialized units also know how to access and use information from PDMPs, and working with prosecutors who litigate prescription diversion cases helps develop expertise about the effective collection of evidence necessary to obtain convictions. There is also undercover specialization, such as making the prescription drug diversion equivalent of a controlled buy with agents posing as customers to confirm doctor's illegal issuance of narcotics prescriptions.

If the investigation moved too rapidly to refer to the diversion task force, or was an interdiction opportunity, the task force would keep the case. For example, over the previous five years there have been a small number of cases focused on burglarizing pharmacies, and then trafficking the pills. Aside from the fact that the drugs are pharmaceuticals and had been stolen, the operations and the scope and methods used in the investigation were similar to the smuggling and distribution of any other illegal drugs, and were handled by collaborations of local law enforcement and HIDTA enforcement initiatives.

As reflected above, some diversion investigations parallel traditional narcotics investigations, where drugs are moving from one illegal source of supply to another. The difference is that diversion investigations involve the prescription drugs being redirected from medical to non-medical use. In some patient-centered cases, e.g., patient selling excess pills that were legitimately obtained to make a profit or a non-patient fraudulently obtains pills for personal use the investigation is fairly standard and limited to the few individuals involved.

Diversion Investigations by Federally-led Task Forces. Other cases involve DTOs amassing large quantities of pills through diversion and may include manufacturers, practitioners, pharmacies, patients, and/or non-patients. In these cases, law enforcement addresses both the practitioners, who may be illegally prescribing and/or dispensing controlled prescription drugs, non-patients who are involved in doctor shopping or other fraudulent activity to illegally obtain controlled prescription drugs, as well as drug dealers and DTOs that may be relying on practitioners or patients to divert controlled prescription drugs to sell on the retail market.

These investigations may not include traditional investigative strategies and require resources and expertise specific to diversion investigations. The DEA's Office of Diversion Control through its oversight role over practitioners authorized to prescribe and dispense controlled prescription drugs is staffed with diversion investigators, special agents, chemists, pharmacologists, program analysts, and others that are tasked with preventing, detecting, and investigating the diversion of controlled prescription drugs.⁶⁵

There are two main tactics implemented by the DEA to address the diversion problem.

⁶⁵ For more information on the DEA's Office of Diversion Control, see <u>http://www.deadiversion.usdoj.gov/prog_dscrpt/index.html</u>. Retrieved January 23, 2015.

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- Diversion Investigators conduct regulatory investigations across the different registrant categories (e.g., manufacturers, importers, exporters, distributors, narcotics treatment programs, researchers) to ensure registrants are complying with regulations established by the CSA. Non-compliance may result in administrative action and even civil charges.
- DEA Tactical Diversion Squads (TDS) that are staffed with special agents, diversion investigators, and state and local task force officers focus on disrupting and dismantling groups and organizations involved in diversion schemes. Diversion schemes may range from practitioners selling pills or prescriptions to drug dealers, to dealers using a stolen DEA registration number to forge prescriptions, to organized doctor shopping rings.⁶⁶

The DEA TDSs may be involved in the HIDTA program as one of the task forces participating in the program, through the assignment of a diversion investigator to a DEA-led HIDTA task force, or, as reflected above, a HIDTA task force may refer cases to the TDS.

The most common DEA prescription drug diversion investigation involves diversion by unscrupulous doctors. Doctors are in a good position to facilitate or operate a prescription drug trafficking organization and may be corrupted by the possibility of generating considerable revenue by fraudulently writing prescriptions for their trafficking partners. In turn, the partners fill the prescriptions and sell the pills. Investigations of unscrupulous doctors are wide ranging. For example, in January 2014, Dr. Najam Azmat, of Waycross, Georgia, was found guilty of a 51 count indictment. He was charged with running a "pill mill" and conspiring to dispense oxycodone without legitimate medical purposes. As part of a plea agreement, over \$2 million stemming from unlawful activity was forfeited.⁶⁷ In March 2013, an investigation uncovered more than \$10 million in narcotic pills diverted into the tristate area from Manhattan by Dr. Hector Castro. Dubbed "Operation Cuba Libre," the 15-month investigation culminated with the arrests of 49 co-conspirators.⁶⁸ Similar DEA investigations can be found throughout the country.

In addition to launching local area and regional investigations, the DEA also conducts nationwide operations. Called Operation Pill Nation, the DEA coordinated several takedowns of clinicians, pharmacies, DTOs, and doctors illegally distributing prescription drugs. During the second phase of the operation, seven doctors, three clinic owners and one of their relatives were charged with racketeering and other criminal violations in South Florida.⁶⁹

⁶⁶ Leonhart, M. (2011). Warning: The Growing Danger of Prescription Drug Diversion. Statement for the Record before the Subcommittee on Commerce, Manufacturing and Trade Committee on Energy and Commerce, United States House of Representatives. <u>http://www.dea.gov/pr/speeches-testimony/2012-</u> 2009/110414 testimony.pdf. Retrieved January 26, 2015.

⁶⁷ Drug Enforcement Administration. (2014). "Jury Finds Pill-Mill Doctor Guilty of 51 Counts: In total, 10 defendants convicted and \$2 million forfeited relating to the prosecution of a phony pain clinic in Garden City, Georgia." <u>http://www.dea.gov/divisions/atl/2014/atl012314.shtml</u>. *DEA: Press Release*.

⁶⁸ Drug Enforcement Administration. (2013). "Gramercy Medical Center Pumped More Than \$10 Million in Narcotic Pills onto Interstate Black Market Physician and Office Manager among 49 arrested in New York, New Jersey and Pennsylvania: 30 guns seized." <u>http://www.dea.gov/divisions/nyc/2013/nyc032813.shtml</u>. *DEA: Press Release*.

⁶⁹ Drug Enforcement Administration. (2012). "Operation Pill Nation Strikes Again with Phase II Takedown." <u>http://www.dea.gov/divisions/mia/2012/mia081612p.html</u>. DEA: Press Release.

Accompanying the nationwide crackdown on unscrupulous doctors, the DEA also targets Internet pillmills, facilitators of prescription drug diversion, and poly-drug trafficking organizations. In April 2012, the DEA and Department of Justice were able to win a \$500,000 settlement from The Kundrat Corporation. Operated out of Ann Arbor, Michigan, The Kundrat Corporation used connections with Florida pill-mills to distribute hydrocodone throughout the United States. The Kundrat Corporation worked with several doctors throughout the United States to authorize the prescriptions of controlled substances over the Internet. The doctors, however, had not examined the patients they were prescribing for, which is "outside the usual course of professional practice."⁷⁰

The DEA also investigates facilitators of illegal Internet pharmacies. In 2014, FedEx was charged with conspiring to traffic controlled substances from internet pharmacies. Members of the DEA, FDA, and Congress had warned FedEx that internet pharmacies were using their services to illegally send drugs across the country. Starting in 2000, FedEx began working with Vincent Chhabra, the operator of the Chhabra-Smoley Organization, which did not require patients meet with a physician to get a prescription filled. Despite the warnings, FedEx continued facilitating the illegal shipment of prescription drugs.⁷¹

The DEA also investigates traditional DTOs that have diversified into trafficking prescription drugs, as many major crime syndicates have entered the black market for prescription drugs. For example, known as "the syndicate," the Albanian mob obtained oxycodone diverted from Florida pill-mills to sell in New York. In addition to seizing thousands of diverted oxycodone units, over 1,200 pounds of marijuana and hundreds of pounds of cocaine attributed to this DTO were also seized.⁷²

Other federal agencies (e.g., Centers for Medicare & Medicaid Services, Food and Drug Administration, Office of the Inspector General) may also investigate prescription drug diversion cases. Although these investigators have not been traditionally part of HIDTA enforcement initiatives, the New Mexico HIDTA is considering establishing a diversion initiative that include representatives from DEA, FBI, NM State Police, Board of Pharmacy, US Attorney and Medicare & Medicaid fraud investigation units to create a multi-pronged approach targeting doctors, particularly those filing fraudulent claims to Medicare/Medicaid as part of diversion strategy. This could result in administrative sanctions as well as criminal charges.

Drug Disposal Programs

Both federal and non-federally led HIDTA task forces may also be involved in the disposal of medication through their participation in either the national drug "take-back" program or local "take-back" efforts. Whether a national or local effort, drug "take-back" events have been established around the country to provide an environmentally-friendly option for disposing of medications, particularly controlled substances, and removing the possibility of them entering the black market.

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⁷⁰ Drug Enforcement Administration. (2012). "DEA Diversion Investigation Leads to \$500000 Settlement in Internet Pharmacy Case." <u>http://www.dea.gov/divisions/det/2012/det043012p.html</u>. DEA: Press Release.

⁷¹ Drug Enforcement Administration. (2014). "FedEx Indicted for Its Role in Distributing Controlled Substances and Prescription Drugs." <u>http://www.dea.gov/divisions/sf/2014/sf071814.shtml</u>. *DEA: Press Release*.

⁷² Drug Enforcement Administration. (2014). "Leader and a Member of an International Ethnic-Albanian Organized Crime Syndicate Sentenced to 120 Months and 110 Months Respectively for Drug Trafficking." <u>http://www.dea.gov/divisions/nyc/2014/nyc021414a.shtml</u>. *DEA: Press Release*.

Up until about ten years ago, general practice was to flush unused, unwanted, or expired medication down the sink or toilet, throw it in the trash, or let it accumulate in one's medicine cabinet, all of which were consistent with the guidance that was being provided at the time by practitioners, as well as the Federal government.⁷³ But what had become common practice began to be questioned because of the risks these practices posed to both the environment and public safety.

Although alternate options were desirable, the issue, at the time, was that under Federal law, practitioners (DEA registrants) were not allowed to acquire controlled substances from patients or long term care facilities (non-registrants), even if the substances were expired or unused by the patient for which it was prescribed.⁷⁴ So, unless DEA granted permission and law enforcement officers were present to take possession of controlled substances, state and local drug disposal programs could not legally accept controlled substances, even if receptacles were located at pharmacies.⁷⁵

The Secure and Responsible Drug Disposal Act of 2010 opened up the pathway for drug disposal programs to more readily accept controlled substances and resulted in regulations, which were put into effect in 2014 and allowed registrants to modify their DEA registration to obtain authorization as an authorized collector. This means they can maintain collection receptacles inside their location and those with an on-site method of destruction may operate mail-back programs. Authorized collectors, community groups or other non-registrants are still not authorized to conduct take-back events unless in partnership with law enforcement.⁷⁶

Current guidance to consumers from EPA, FDA, and ONDCP now recommends drug take-back programs as the preferred option for disposal of unused medicines, and, if these programs are not available, to limit the flushing of medicine down the sink or toilet to those that specify this mode of disposal on the prescription label. Additionally, throwing away medicine should only be done after mixing it with undesirable substance, placing it in a sealable bag, and removing or blacking out labels on containers.⁷⁷

The DEA has been sponsoring national drug take-back programs since 2010, when it collected more than 242,000 pounds of prescription drugs at the first national take-back event.⁷⁸ Since then, there have been

⁷³ Herring, M. E., Shah, S. K., Shah, S. K., & Gupta, A. K. (2008). Current regulations and modest proposals regarding disposal of unused opioids and other controlled substances. *Journal of the American Osteopathic Association, 108*(7), 338-343.

⁷⁴ Drug Enforcement Administration. Questions & Answers <u>http://www.deadiversion.usdoj.gov/faq/general.htm</u>. Retrieved February 3, 2015.

⁷⁵ See the Secure and Responsible Drug Disposal Act of 2010 available at <u>http://www.deadiversion.usdoj.gov/drug_disposal/non_registrant/s_3397.pdf</u>. Retrieved February 2, 2015.

⁷⁶ Drug Enforcement Administration. (2014). Disposal Regulations: Registrant Fact Sheet <u>http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_registrant.pdf</u>. United States Department of Justice. Retrieved February 2, 2015.

 ⁷⁷ Food and Drug Administration. (2015). How to Dispose of Unused Medicines. <u>http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm</u>. Retrieved February 3, 2015; Environmental Protection Agency. (2011). How to Dispose of Medicines Properly. <u>http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf</u>. Retrieved February 4, 2015.

⁷⁸ Drug Enforcement Administration. (2010). American Public Overwhelmingly Responds toDEA Prescription Drug Take-Back Effort <u>http://www.dea.gov/divisions/hq/2010/pr100510p.html</u>. DEA: Press Release.

nine national drug take-back efforts that have collected a total of 2,411 tons of prescription drugs through its partnerships with communities and local law enforcement.⁷⁹ As a result, DEA-led HIDTA task forces may be involved in supporting national take-back events in their region.

Before the DEA began organizing national take-back programs, local communities and states began establishing their own guidance and organizing efforts to dispose of uncontrolled pharmaceuticals or dispose of controlled substances that was compliant with CSA regulations, i.e., involve law enforcement in the collection, since before passage of the Act in 2010.⁸⁰

Since then, a number of localities across the country have established programs to dispose of unwanted or unused controlled substances that vary in sponsor, goals, scale (one day versus ongoing), and mode of collection (drop-off sites, scheduled collection days and events, mail-back). Program goals range from public awareness of the environmental risks posed by flushing or throwing away prescription drugs, reducing identity theft (because of personal information maintained on bottles), preventing secondhand use of medication, and protecting citizens, especially the elderly, from drug theft.⁸¹

One example is a pharmaceutical drug take-back program operating in San Juan County New Mexico that involves a partnership between the San Juan Safe Communities Initiative, the San Juan Regional Medical Center, and five different law enforcement agencies, including the San Juan County Sheriff's Office and the HIDTA task force led by representatives from the Sheriff's Office. The take-back program operates year-round, accepting prescription drugs and over the counter medication for disposal using take-back boxes located in the lobbies of each of the partnering law enforcement agencies, which are given to DEA for disposal at national drug take-back events.⁸² The HIDTA task force supervisor involved in the program reported that he attributes the program success—which he bases on the hundreds of pounds of prescription pills and anecdotal information from practitioners that they are seeing fewer youth overdoses— to the partnership with San Juan Safe Communities program, as well as local hospitals and pharmacies to support education and marketing efforts.⁸³

In some cases, program goals may be expanded, as is the case with the program operated by the Snohomish County Sheriff's Office in Washington State, of which the HIDTA's Snohomish Regional Drug Task Force (SRDTF) is a partner. Similar to the program in San Juan, New Mexico, the Snohomish program is perpetual, with secure boxes available year-round in multiple locations, but the program has

⁷⁹ Drug Enforcement Administration. (2014). DEA and Partners Collect 309 Tons of Pills on Ninth Prescription Drug Take-Back Day <u>http://www.dea.gov/divisions/hq/2014/hq110514.shtml</u>. *DEA: Press Release*. Retrieved on February 3, 2015.

⁸⁰ See the Center for Substance Abuse Research for compendium of pending and approved state legislation related to the disposal of unused prescription drugs. <u>http://www.cesar.umd.edu/cesar/library/statutes.asp#labl.</u> Retrieved February 2, 2015.

⁸¹ Glassmeyer, S. T., Hinchey, E. K., Boehme, S. E., Daughton, C. G., Ruhoy, I. S., Conerly, O., . . . Thompson, V. G. (2009). Disposal practices for unwanted residential medications in the United States. *Environment International*, 35(3), 566-572.

⁸² For more information on the San Juan Safe Communities Initiative, see <u>http://www.sjsci.org/#!rx-disposal/clng</u>. Retrieved February 23, 2015.

⁸³ Interview Notes with Region II Task Force, June 2014.

also involved efforts to study the pharmaceuticals collected, and to use such information strategically. For example, patterns in the collection of controlled substances can be triangulated with other information sources to develop a picture of the availability of pharmaceuticals in the county, and tracking such information over time can contribute to intelligence about drug abuse trends.

This program was launched in 2009, and was developed in response to the high rate of youth drug overdose deaths in Snohomish County (higher than traffic accident deaths). The county also wanted to decrease the detrimental environmental effects of people dumping their unwanted medications in the trash or disposing of them in toilets or sinks. Studies of local drinking water showed traces of antibiotics, controlled substances, and estrogen from discarded contraceptive pills.

The program is coordinated by the Snohomish County Partnership for Secure Medicine Disposal, in partnership with the SRDTF, Snohomish Health District, Snohomish County, the Snohomish County Sheriff's office, Washington State Patrol, and all local law enforcement agencies. Secure take-back boxes are present at every police station in Snohomish County. There are also boxes in two jails, the NCIS office at Naval Station Everett for those with access, and tribal police stations on the Tulalip and Stillaguamish reservations. Two Group Health site and several Bartell drugstores in Snohomish County also collect unwanted medicines. All sites accept unwanted vitamins, pet medications, over-the-counter medications, inhalers, and unopened EpiPens; however, only law enforcement locations can collect controlled substances.⁸⁴

When the boxes are full, a police officer will call the designated member of the SRDTF to gather the contents of the boxes and place them in evidence storage until the DEA hosts the National drug take-back and contents are then delivered to the DEA for disposal. The Task Force's annual report details the quantity of drugs, in pounds, they gathered from the community. About 8,000 lbs. were collected in 2013, and amounts have increased every year since the program began in 2009. As stated above, an important extension of the DEA model of drug take-back programs is the analysis of the drugs gathered. Prior to 2014 they initiated a "content study"— boxes are selected at random and a pharmacist is hired to examine the contents to create a profile of what types of drugs they are collecting.⁸⁵

Prescription Drug Monitoring

One of the action areas identified in the Prescription Drug Abuse Prevention Plan is tracking and monitoring prescription drugs.

As described above, controlled prescription drugs may be diverted through doctor shopping or by unscrupulous physicians taking advantage of the lack of monitoring of the prescribing and dispensing of controlled prescription drugs within or across states. Prescription Drug Monitoring Programs (PDMPs) provide prescribers and dispensers information about specific patients' prescription histories (for those drugs monitored in the state and, in some cases, other states) to assist prescribers in documenting patients histories and to detect or prevent doctor shopping.

⁸⁴ For more information on the Snohomish County Partnership for Secure Medicine Disposal Program, see <u>http://www.srdtf.org/snohomish-county-partnership-secure-medicine-disposal-program.</u> Retrieved February 23, 2014.

⁸⁵ Interview Notes with Snohomish Regional Drug Task Force, April 2014.

The earliest PDMPs were paper-based, but the newer generations of PDMPs employ computer-based information technologies for speedier reporting by all dispensers in a state. Since FY 2002, the federal government has supported the creation or enhancement of state PDMPs under the authority of the Harold Rogers Prescription Drug Monitoring Program, administered jointly by the Department of Justice's Bureau of Justice Assistance and the Drug Enforcement Administration.⁸⁶ Additional grant support became available from the Department of Health and Human Services (DHHS) with passage of the National All Schedules Prescription Electronic Reporting Act (NASPER) in 2005. Currently 49 states, the District of Columbia, and Guam have fully implemented PDMPs that are collecting data and reporting information.⁸⁷

While there are a number of commonalities across state PDMPs, there are also some differences in the functionality of PDMPs and accessibility of PDMP information, particularly among law enforcement. To better understand differences in PDMPs across states, we researched the PDMPs in the eight states covered by the three HIDTAs targeted for this study. For each state, researchers reviewed publically available information about the PDMP, and conducted telephone interviews with representatives from PDMPs in Maine, New Mexico, and Washington State.

PDMP Functionality

While a few PDMPs were established in the 1970s, most PDMPs have been established over the last twenty years.⁸⁸ As reflected in Table 1, among the eight states, Rhode Island's PDMP has been operational the longest, since 1979, while New Hampshire's PDMP became operational in 2014.

All state monitoring systems require dispensers to report prescription information for all dispensed Schedule II drugs; some require reporting for other scheduled drugs, as well as some non-scheduled, but abused drugs.⁸⁹ All eight states' PDMPs monitor dispensed schedule II – IV controlled prescription drugs, but Connecticut, Massachusetts, New Mexico, and Washington monitor schedule V controlled prescription drugs as well.

⁸⁶ The Prescription Drug Monitoring Program was created by the FY 2002 U.S. Department of Justice Appropriations Act (Public Law 107-77). See descriptions of the program at <u>https://www.bja.gov/ProgramDetails.aspx?Program ID=72</u> Retrieved February 13, 2015.

⁸⁷ Prescription Drug Monitoring Program Training and Technical Assistance Center. Prescription Drug Monitoring Frequently Asked Questions (FAQ). <u>http://www.pdmpassist.org/pdf/pdmp_faq_2014_print.pdf</u>. Retrieved February 26, 2015.

⁸⁸ See the National Alliance for Model State Drug Laws compendium of PDMP Dates of Operation <u>http://www.namsdl.org/library/580225E9-E469-AFA9-50E7579C1D738E71/.</u> Retrieved February 25, 2015.

⁸⁹ Prescription Drug Monitoring Program Training and Technical Assistance Center. Prescription Drug Monitoring Frequently Asked Questions (FAQ) <u>http://www.pdmpassist.org/pdf/pdmp_faq_2014_print.pdf</u>. Retrieved February 26, 2015.

Table 1. PDMP Characteristics⁹⁰

State	PDMP Agency	Year Operational	Schedule Classifications	Responsible for Data Entry	Verification of Patient Prescription History ⁹¹
Connecticut	Department of Consumer Protection	2008	II, III, IV, V	Pharmacy, outpatient pharmacy in a hospital or institution, and dispensers	Voluntary
Maine	Department of Health and Human Services; Office of Substance Abuse and Mental Health Services	2004	II, III, IV	All Dispensers, Pharmacies, or licensed health care professionals	Voluntary
Massachusetts	Department of Public Health; Healthcare Safety and Quality Drug Control Program	1994	II, III, IV, V	All dispensers, including pharmacies and dispensing practitioners	Mandatory
New Hampshire	New Hampshire Pharmacy Board	2014	II, III, IV	Lawfully authorized persons to deliver a controlled substance	Voluntary
New Mexico	Regulation & Licensing Department; Board of Pharmacy	2005	II, III, IV, V	All persons lawfully authorized to deliver a controlled substance	Mandatory
Rhode Island	Department of Health	1979 ⁹²	II, III, IV	Pharmacies (retail and institutional)	Mandatory
Vermont	Department of Health	2009	II, III, IV	All dispensers licensed by the Board of Pharmacy	Mandatory
Washington	Department of Health	2012	II, III, IV, V	Practitioners or pharmacies that deliver scheduled substances	Voluntary ⁹³

Across PDMPs, the majority of state programs are housed in boards of pharmacy or other licensing boards, while a smaller number are operated by law enforcement or health departments. In most cases, the

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⁹⁰ National Alliance for Model State Drug Laws. State Profiles. <u>http://www.namsdl.org/prescription-monitoring-programs.cfm.</u> Retrieved March 4, 2015.

⁹¹ Information presented reflects the extent to which legislation requires prescribers and/or dispensers to access PMP data in certain circumstances.

⁹² Prescription Drug Monitoring Program Training and Technical Assistance Center. Rhode Island State Profile. www.pdmpassist.org/content/Rhode-Island-state-profile. Retrieved March 4, 2015.

⁹³ Interview Notes with Washington State Department of Health Prescription Monitoring Program. February 23, 2015.

agency administering the PDMP programs in the eight states is the state's Department of Health. The exceptions are the PDMPs in New Hampshire and New Mexico, which are both overseen by the Board of Pharmacy.

In most states, data are entered by the pharmacy and prescribers with the ability to dispense controlled substances. While all of the eight PDMPs require pharmacies to report dispensing of controlled prescription drugs (including those shipping from out of state), there are some minor differences from state to state in the extent to which practitioners (with the authority to dispense controlled substances) or independent pharmacies are required to report to the state PDMP.

For example, all pharmacies in New Mexico, as well as any mail order business outside of New Mexico that ships controlled substance products to patients in the state are required to submit information to the state PDMP. Additionally, prescribers, if dispensing more than three days' supply of a controlled substance from their office must enter data into the PDMP.⁹⁴ Washington also requires both pharmacies and practitioners with the authority to dispense schedule II - V controlled substances to report to the PDMP. However, although pharmacies and dispensers are required to enter data into the PDMP, there is no legal requirement in the Washington PMP statute that dispensers check a patient's prescription history prior to prescribing/dispensing narcotics.⁹⁵ This is not unusual, as Connecticut, Maine, and New Hampshire also do not require practitioners/pharmacies/dispensers to check PDMPs before prescribing/dispensing. There is legislation (LD327/127th legislature) pending in Maine that would require prescribers to check PDMP data before prescribing.

While there may be some differences in the information collected by state PDMPs, the type of information collected by the Connecticut, Maine, Massachusetts, New Hampshire, New Mexico, Rhode Island, Vermont, and Washington PDMPs is fairly consistent and covers information on patient (e.g., name, address, date of birth), prescriber (e.g., DEA number), dispenser/pharmacy (e.g., DEA number of pharmacy), prescription information (e.g., what was prescribed, date filled, new or refill, dose, how many days supply), and how the prescription was paid for.⁹⁶

Sharing PDMP Information

Doctor shoppers who are intent on evading surveillance by state PDMPs can purchase drugs from pharmacies in different states. Many states are seeking to remedy this shortcoming by establishing agreements to share PDMP data, thereby enhancing the ability of law enforcement agencies as well as physicians to spot patients who appear to be purchasing drugs for diversion to nonmedical use—or patients who are at high risk for overdose.

All eight states have the ability to share information with certain other states, but may differ on the extent to which they are accessing other state's PDMP information. For example, the Washington PDMP has the capability to be linked to PDMP systems in other states, but data sharing agreement issues have prevented

⁹⁴ Interview Notes with New Mexico Board of Pharmacy Prescription Monitoring Program, February 23, 2015.

⁹⁵ Interview Notes with Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

⁹⁶ See state profiles for CT, ME, MA, NH, NM, RI, VT, and WA maintained by the National Alliance for Model State Drug Laws that are available at <u>http://www.namsdl.org/prescription-monitoring-programs.cfm</u>. Retrieved on March 4, 2015.

sharing to date.⁹⁷ New Mexico's PDMP system is currently connected to additional states, however, law enforcement agencies registered as PDMP users in New Mexico are restricted to only accessing information within New Mexico. The New Mexico PDMP system is connected to PMP Interconnect, which links 22 PDMPs. The information shared on the Interconnect system is determined by each state's PDMP program. If, for example, Colorado restricted access from nurses in their state, then nurses in other states would not be able to access that information, even if they were able in their home states.⁹⁸

Additionally, Maine's PDMP is linked to the PDMP's in Kentucky and Alabama, though not connected regionally to neighboring states. This is because of the barriers existing with different state laws and policies regarding PDMP information sharing. Maine has an agreed upon Memorandum of Understanding (MOU) with Kentucky and Alabama because they have similar language pertaining to their PDMPs and use similar information hubs. Agreements on what and how information is shared is pertinent to the protection of the PDMP information.

Law Enforcement Access

PDMPs also support law enforcement investigations. Before PDMPs existed, investigators had to make inquiries at multiple pharmacies to develop information about suspects and many pharmacies were reluctant to provide the data. Centralized prescription data supplied by PDMP systems can quickly provide information about drugs purchased, the identity of their prescribers and dispensers, amounts purchased, dates of purchase, and method of payment. However, the laws governing access to prescription information contained in these PDMPs vary significantly from one state to another and thereby provide different capacities to law enforcement agencies for investigation and prosecution. To protect the rights of patients who may become potential suspects, most states' PDMPs limit law enforcement officers direct access, typically by allowing release of information about only those persons who are subjects of an active investigation, whether they be patients, physicians, or pharmacists.⁹⁹

As reflected in Table 2, the eight PDMP programs have operational and accessibility differences in their approach to data collection and sharing with law enforcement.

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⁹⁷ Interview Notes Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

⁹⁸ Interview Notes New Mexico Board of Pharmacy Prescription Monitoring Program, February 23, 2015.

⁹⁹ For more specific information regarding law enforcement access, see individual state profiles on Prescription Drug Monitoring Programs compiled by the National Alliance for Model State Drug Laws (NAMSDL) at <u>http://www.namsdl.org/library/BCEA5CFB-E29A-B561-3B62960EF453D9B3/. Accessed February 24, 2015.</u>

State:	Law Enforcement PDMP Registered Users:	Law Enforcement Access Requirements:
Connecticut	Yes	Probable Cause ¹⁰⁰
Maine	No	Grand Jury Subpoena ¹⁰¹
Massachusetts	Yes	Probable Cause ¹⁰²
New Hampshire	No	Request Form ¹⁰³
New Mexico	Yes	Request Form submitted with Court Order ¹⁰⁴
Rhode Island	No	Search Warrant ¹⁰⁵
Vermont	No	No Law Enforcement Access ¹⁰⁶
Washington	Yes	Probable Cause ¹⁰⁷

Table 2. Law Enforcement Access to PDMP Data

The eight states range both on whether and how law enforcement may access PDMP data. While Vermont does not provide access to law enforcement,¹⁰⁸ the other seven states provide direct access to registered users or provide information upon authorization from the courts via court order, subpoena, or warrant.

Access to data by law enforcement is not necessarily given directly to investigators. For example, Maine's PDMP system is not directly accessible to investigatory law enforcement agencies, but the information can be delivered to them when a grand jury subpoena is provided. It is typically through the

¹⁰⁰ Connecticut Department of Consumer Protection Prescription Monitoring Program. "Log On. Save Time. Close Cases. An Effective Law Enforcement Tool for Conducting Prescription Fraud Investigations." <u>http://www.ct.gov/dcp/lib/dcp/drug_control/pmp/pdf/dcple.pdf.</u> Accessed March 9, 2015

¹⁰¹ Interview Notes Maine Dept. of Health & Human Services – Substance Abuse and Mental Health Services Prescription Monitoring Program, February 27, 2015.

¹⁰² National Alliance for Model State Drug Laws. (2014). Prescription Monitoring Program State Profiles – Massachusetts. Page 9. <u>http://www.namsdl.org/library/22EFDB91-A4FB-B98B-51007F37316A19F2/</u> Accessed March 9, 2015

¹⁰³ National Alliance for Model State Drug Laws. (2014). Prescription Monitoring Program State Profiles – New Hampshire. Page 6. <u>http://www.namsdl.org/library/27A8375F-BDAA-B4CF-B3710D2CAD617CFF/</u> Accessed March 9, 2015

¹⁰⁴ Interview Notes New Mexico Board of Pharmacy Prescription Monitoring Program, February 23, 2015.

¹⁰⁵ National Alliance for Model State Drug Laws. (2014). Prescription Monitoring Program State Profiles – Rhode Island. Page 3. <u>http://www.namsdl.org/library/2AF59EA3-B769-A306-B081C5CA6D789117/</u> Accessed March 9, 2015

¹⁰⁶ Vermont Department of Health. Vermont Prescription Monitoring System (VPMS) Frequently Asked Questions. <u>http://healthvermont.gov/adap/documents/VPMSFAQs.pdf.</u> Accessed March 9, 2015.

¹⁰⁷ Interview Notes Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

¹⁰⁸ However, the overseeing Licensing Board may notify law enforcement if they find within the PDMP database that there is evidence of illegal activity.
Attorney General's office, once the subpoena has been issued, that the PDMP data would be shared with investigators.¹⁰⁹

Four state PDMPs allow law enforcement personnel to register as users and directly access PDMP information, provided there is some form or mechanism confirming the validity of their searches. In New Mexico, for example, registered law enforcement investigators must be vetted prior to being given access to the PDMP. Any law enforcement agent who becomes a registrant goes through an application process, and controlled substance investigations must be the scope of their work. Once they have met the registration requirements, they have the ability to run reports on active investigations as any other user would. There is no formal coursework required for law enforcement prior to becoming a registrant though they have the option to take an online training. There is no restriction placed on their access other than a prohibition on accessing information from PDMP systems outside of New Mexico. This has been the policy since the PDMP was implemented.¹¹⁰ Washington State law enforcement agencies are also able to register as PDMP users. This is done using a two-tier system: the agency head, or an approved subordinate, registers as the "Master Account." This then allows investigators under the "Master" register as "Delegates." The "Master Account" reviews the information requests on a monthly basis and assesses their legitimacy. Currently the registered law enforcement agencies consist of the DEA, Washington State Patrol, Drug Task Forces (including the Northwest HIDTA), the FBI, U.S. Coast Guard, U.S. Health and Human Services Medicare Fraud Unit, and other State & local law enforcement offices. In addition to these law enforcement agencies, medical examiners and coroners are also able to access the PDMP system when trying to determine a cause of death.¹¹¹

Both New Mexico and Washington grant law enforcement agencies access to their systems, but still receive requests from law enforcement agencies not registered as users. These requests come in written forms. Both states report the time to process written requests take between two and three days, as opposed to the immediate response users would receive.

The other three PDMPs allow access to law enforcement agencies that are not registered as users, but generally require some type of application to be submitted that specifies patient information and the information of interest. This request often requires that a subpoena or warrant accompany the request form.

In Washington, for example, there are specified search parameters by which law enforcement can review information; investigators must enter an investigative case number and can query information on prescriptions by patients, prescribers, and dispensers. The Washington PDMP system's ability to produce a "shopping list" (ex: *pharmacy locations, prescribers, patient residence*) of information that allows users to narrow in on the prescription records needed for their investigation. Investigators are able to determine what prescriptions were filled, what the dosage was, what the strength of the prescription is, how much was prescribed, who prescribed the drug, where it was dispensed, etc. The system's search restrictions mitigate attempts to data mine. The system's mapping feature allows investigators to plot the patient's address relative to the pharmacies and prescribers they are utilizing, and how frequently they are visiting

¹⁰⁹ Interview Notes Maine Dept. of Health & Human Services – Substance Abuse and Mental Health Services Prescription Monitoring Program, February 27, 2015.

¹¹⁰ Interview Notes New Mexico Board of Pharmacy Prescription Monitoring Program, February 23, 2015.

¹¹¹ Interview Notes Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

pharmacies in particular locations. The PDMP administrator feels these features balance efficiency and practicality while maintaining patient confidentiality.¹¹²

While there is growing evidence of the value of PDMPs to law enforcement investigations,¹¹³ some state legislatures face greater pushback from advocacy groups and medical professionals when debating legislation related to law enforcement access. For example, in 2013 the Massachusetts legislature sought to enhance their PDMP. Adopted in 1992, Massachusetts had archaic systems in place, lacking internet accessibility and requiring substantial time (up to three weeks) to obtain access to reports.¹¹⁴ When discussing changes to the existing program, the Massachusetts Medical Society (MMS) argued that the rigorous oversight proposed in the legislation would place a heavy burden on medical professionals.¹¹⁵ Similar criticisms of expanding PDMPs can be found in other states. For example, Dr. Kenneth L. Bakken, a preventative medicine and pain management specialist, opined that changes to the Washington PDMP were, "well-intentioned but intrusive for conscientious clinicians and patients."¹¹⁶

Marketing to Law Enforcement

The states also vary in their marketing of the PDMP to the law enforcement community. For example, Connecticut actively markets to law enforcement agencies, encouraging them to register with their system.¹¹⁷ Massachusetts' recently elected Attorney General made increasing law enforcement access to PDMP's a major point of emphasis of her administration.¹¹⁸

Washington has made some efforts to market the PDMP to law enforcement agencies in the state. Its efforts to expand awareness of the program and enrollment began in early 2012, through webinars and

¹¹² Interview Notes Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

PDMP Center of Excellence. (April 2013). Briefing on PDMP Effectiveness
 <u>http://www.pdmpexcellence.org/sites/all/pdfs/briefing_PDMP_effectiveness_april_2013.pdf</u>. Brandeis
 University, The Heller School. Retrieved February 26, 2015.

¹¹⁴ Blumenschein, K., Fink, J. L., Freeman, P. R., James, K., Kirsh, K., Steinke, D. T., & Talbert, J. (June 2010). Review of Prescription Drug Monitoring Programs in the United States - Kentucky All Schedule Prescription Electronic Reporting Program (KASPER) Evaluation Team <u>http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf</u>. Accessed February 25, 2015.

¹¹⁵ Gulla, R. (2013). Massachusetts Medical Society Testifies in Opposition to Proposed Regulations of Prescription Monitoring March 22,2013 <u>http://www.massmed.org/News-and-Publications/MMS-News-Releases/Massachusetts-Medical-Society-Testifies-in-Opposition-to-Proposed-Regulations-of-Prescription-Monitoring-Program/#.VOz6XSzD_pl. Massachusetts Medical Society. Accessed February 24, 2015.</u>

¹¹⁶ Schierhorn, C. (January 30, 2012). Washington State's New Drug Monitoring Program Pits Safety Against Privacy <u>http://thedo.osteopathic.org/2012/01/washington-states-new-drug-monitoring-program-pits-safety-against-privacy/</u>. *American Osteopathic Association*. Retrieved February 26, 2015.

¹¹⁷ Connecticut Dept. of Consumer Protection – Prescription Monitoring Program – "Law Enforcement – Log On. Save Time. Close Cases" <u>http://www.ct.gov/dcp/cwp/view.asp?Q=477578&dcpNav_GID=&dcpNav. Accessed February 12, 2015.</u>

¹¹⁸ Maura Healey for Attorney General. (January 2015). "Healey Launches Extensive Opiate/Prescription Drug Effort." <u>http://www.maurahealey.com/news/post/2015-01-healey-launches-extensive-opiateprescription-drug-</u> <u>ef</u>. Retrieved February 20, 2015.

onsite trainings. The awareness trainings have also functioned as an opportunity to provide law enforcement with updates on deaths related to controlled substance prescriptions overdoses, treatment admissions, and the impact that the PDMP is having. Presentations were also made to the Washington Association of Sheriffs and Police Chiefs and the Northwest HIDTA.

The Washington PDMP also seeks feedback related to the performance of the system, though not its usefulness in investigations. While most of the feedback has been positive, there have been a number of requests to enable the system to produce CSV or Excel spreadsheets for users to download along with search results (Currently, the system is only able to produce a printout or PDF, resulting in investigators having to read through the document rather than be able to sort the information to easily identify what they're looking for).¹¹⁹

While New Mexico does not currently have a plan for marketing the PDMP to law enforcement agencies in the state, the program does encourage its use to increase registrants. And, if successful, the program is considering the development of a feedback mechanism.¹²⁰

Unsolicited Reporting

PDMPs offer the opportunity for still more powerful investigative tools in some states —searching (or "mining") the data to identify patients whose patterns of acquiring drugs look suspicious—for example, obtaining prescriptions for opioids from different physicians within a short period of time and filling them at different pharmacies. Such 'proactive' searching was not permitted by statute in most states that had established PDMPs prior to 2005,¹²¹ but most PDMPs now have the authority and the required resources to conduct proactive searches and then alert prescribers, pharmacists, licensing entities, or law enforcement through unsolicited reports.¹²² The DHHS grants authorized under NASPER have been encouraging this by requiring proactive searching for patients who may be doctor shoppers and then sending out unsolicited reports to relevant prescribers and dispensers.

All eight PDMP systems can generate threshold (unsolicited) reports to alert prescribers to patients who trigger pre-determined parameters within the PDMP system, but vary as to who is able to receive these reports.^{123,124} For example, the New Mexico PDMP sends an e-mail to prescribers when a patient has been to five or more different prescribers or five or more different pharmacies within a six month period. The PDMP coordinator reviews and approves each unsolicited report generated by the system prior to it being

¹²³ Ibid.

¹¹⁹ Interview Notes Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

¹²⁰ Interview Notes New Mexico Board of Pharmacy Prescription Monitoring Program, February 23, 2015.

¹²¹ McDonald, D., Hurd, D. D., Loyd-Kolkin, S., Hamilton, C., Reddy, P., & Adedokun, L. (2004). Prescription Monitoring Programs: Current Practices and Suggestions for Further Research on Their Effectiveness. *Abt Associates*.

¹²² See map of Unsolicited PMP Reports/Alerts to Prescribers, Pharmacists, Licensing Entities, and Law Enforcement compiled by the National Alliance for Model State Drug Laws available at <u>http://www.namsdl.org/library/BDC14250-C636-4E06-3EA3510BB665BF67/</u>. Retrieved March 4, 2015.

¹²⁴ Though Washington has the capability to generate unsolicited reports, it is not utilizing the feature until the University of Washington has completed a study to assess the impact of sending unsolicited reports to prescribers and pharmacists regarding patients determined to be at-risk of overdose.

e-mailed. While these reports are not currently shared with pharmacies, efforts are underway to include them in the distribution. New Mexico is also considering making the unsolicited reports more proactive and automated by notifying a prescriber once the threshold is met rather than on a quarterly basis.¹²⁵ Maine's threshold reporting is also only sent to prescribers. The sole intent of these reports is to make prescribers aware of potential problems so that prescribers are better able to provide improved patient care.¹²⁶

The same technological capacity is, in principle, available to law enforcement and professional medical and pharmacy licensing boards to monitor physicians and pharmacists, but this has been less frequent in practice. What constitutes an 'indicator of suspicion' in physicians' prescribing practices is more controversial than indicators of doctor shopping by patients. For example, it is easier to be confident in suspicions about a patient who obtains prescriptions for the same scheduled opioid from several different doctors in a short period of time and buys the drugs with cash at different pharmacies. It is more difficult to draw conclusions from a PDMP record that a physician who prescribes scheduled drugs far more often than his or her peers can be suspected of facilitating diversion. For example, oncologists are likely to prescribe pain medications far more often than general practitioners. Much more information is needed to sort through PDMP data, only some of which will be in a PDMP.

While all eight states provide unsolicited reports to prescribers, only four of the eight states (Connecticut, Massachusetts, New Mexico, and Rhode Island) forward unsolicited reports that suggest criminal wrongdoing to law enforcement for further investigation.¹²⁷

The agency administering the PDMP may have an investigative unit to initiate investigations, although investigators are often pursuing regulatory rather than criminal charges. For example, the Washington Department of Public Health has an internal investigative component for the different healthcare licensing boards. The various boards utilize the Public Health's Office of Investigation and Inspectors when inappropriate practices are reported. The Office of Investigations and Inspectors will work with law enforcement agencies when they are investigating potential criminal activity, but their focus is on ethical violations and inappropriate practices. The punitive practices of this office are limited to regulatory court proceedings, but do not supplant law enforcement criminal charges.¹²⁸

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¹²⁵ Interview Notes New Mexico Board of Pharmacy Prescription Monitoring Program, February 23, 2015.

¹²⁶ Interview Notes Maine Dept. of Health & Human Services – Substance Abuse and Mental Health Services Prescription Monitoring Program, February 27, 2015.

¹²⁷ See map of Unsolicited PMP Reports/Alerts to Prescribers, Pharmacists, Licensing Entities, and Law Enforcement compiled by the National Alliance for Model State Drug Laws and available at http://www.namsdl.org/library/BDC14250-C636-4E06-3EA3510BB665BF67/. Retrieved March 4, 2015.

¹²⁸ Interview Notes Washington State Department of Health Prescription Monitoring Program, February 23, 2015.

Conclusions

Since the mid-1990s, the misuse of prescription drugs has grown to epidemic proportions. Numbers of drug overdose deaths increased almost 300% between 1995 and 2012 and now exceed traffic accidents as the leading cause of death in the United States.^{129,130} Thirty-nine percent of those deaths in 2012 involved opioid analgesics.¹³¹ Since 2001, deaths from prescription opioids have been twice as frequent as deaths from heroin and cocaine overdoses combined.¹³² The illicit market for controlled prescription drugs is supplied by a number of different diversion channels, including unscrupulous physicians and pharmacists, doctor shopping, sharing or selling pills obtained legitimately, prescription forgery, thefts and robberies, smuggling, or rogue Internet pharmacies.

The President's plan for reducing prescription drug use calls for action to address the abuse of prescription drugs by raising awareness through prevention and education, tracking and monitoring prescription drugs, proper disposal of medications, and targeted enforcement activities.¹³³ The HIDTA program, administered by the Office of National Drug Control Policy (ONDCP) serves as a valuable tool in ONDCP's efforts to respond to the President's call to action. The program provides a vehicle to direct federal support to provide targeted training and intelligence and information sharing to support federal, state, local, and tribal law enforcement agencies across an entire region of the country in their efforts to identify, investigate, and prosecute those involved in the diversion of prescription drugs. It also provides funds to support regional efforts to reduce the demand for illegal drugs through training, education, prevention, and drug take-back programs.

This report provides an overview of the illegal prescription drug threat and the multiple strategies used to divert prescription drugs as introduction to what was learned through the study about responses that are being implemented at the federal, state, and local levels through the HIDTA and PDMP programs. While this report was able to demonstrate how three different HIDTAs applied the flexibility the HIDTA program affords agencies in designated regions to tailor a multi-agency multi-disciplinary response to its regional drug threats, it is important to note that results are limited by the lack of participation of federally-led HIDTA initiatives, hampering our ability to fully explore the unique nature of prescription diversion investigations and the resources applied to these investigations.

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 ¹²⁹ Fingerhut LA, Cox CS. (1998) Poisoning mortality, 1985-1995. *Public Health Rep.* May-Jun 1998;113(3):218-233.

¹³⁰ Warner M, Hedegaard H, Chen L-H. (2014). Trends in Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012. Hyattsville, MD: *National Center for Health Statistics*.

¹³¹ Ibid.

 ¹³² Warner M, Chen LH, Makuc DM. (2009). Increase in fatal poisonings involving opioid analgesics in the United States, 1999-2006. *National Center for Health Statistics Data Brief.* Sep 2009(22):1-8.

¹³³ White House. (2011). Epidemic: Responding to America's Prescription Drug Abuse Crisis <u>http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf</u> Retrieved February 6, 2015.

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